

AD_____

Award Number: W81XWH-04-1-0159

TITLE: Preventing Health Damaging Behaviors and Negative Health Outcomes in Army and Marine Corps Personnel During the First Tour of Duty

PRINCIPAL INVESTIGATOR: Cherrie Boyer, Ph.D.
Mary-Ann Shafer, M.D.

CONTRACTING ORGANIZATION: University of California
San Francisco, California 94143-0962

REPORT DATE: January 2005

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

20050315 002

REPORT DOCUMENTATION PAGEForm Approved
OMB No. 074-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503

1. AGENCY USE ONLY
(Leave blank)**2. REPORT DATE**
January 2005**3. REPORT TYPE AND DATES COVERED**
Annual (1 Jan 2004 - 31 Dec 2004)**4. TITLE AND SUBTITLE**

Preventing Health Damaging Behaviors and Negative Health Outcomes in Army and Marine Corps Personnel During the First Tour of Duty

5. FUNDING NUMBERS

W81XWH-04-1-0159

6. AUTHOR(S)

Cherrie Boyer, Ph.D.
Mary-Ann Shafer, M.D.

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

University of California
San Francisco, California 94143-0962

E-Mail: boyer@itsa.ucsf.edu

**8. PERFORMING ORGANIZATION
REPORT NUMBER****9. SPONSORING / MONITORING
AGENCY NAME(S) AND ADDRESS(ES)**

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

**10. SPONSORING / MONITORING
AGENCY REPORT NUMBER****11. SUPPLEMENTARY NOTES****12a. DISTRIBUTION / AVAILABILITY STATEMENT**

Approved for Public Release; Distribution Unlimited

12b. DISTRIBUTION CODE**13. ABSTRACT (Maximum 200 Words)**

Health damaging behaviors of young military personnel are reflections of health problems facing all young people in the US. Military life presents opportunities and challenges that may both protect and place young troops at risk for health damaging behaviors. Challenges for maintaining a healthy armed force include high rates of sexually transmitted infections (STIs), unintended pregnancies (UIPs), misuse of alcohol/substances, and sexual violence. The common thread through these negative health outcomes is volitional behavior. Such behaviors not only result in illness or injury, but also negatively impact performance of military duties and threaten military readiness. Despite military leadership in setting standards and policies regarding professional behavior and universal health care for preventing and eliminating such negative health outcomes, many health problems remain.

Building on our previous military research, we plan to develop and evaluate a cognitive-behavioral, skills-building intervention to prevent and reduce young troops' risk for STIs, UIPs, alcohol/substance misuse, and sexual violence. Given current trends toward integrated military training of males and females, this research also seeks to establish the best training practices for educating young troops about health issues that impact military performance and readiness. This research will have direct application for health promotion and disease prevention education strategies designed to reach military men and women early in their careers.

14. SUBJECT TERMS

Health promotion, disease prevention, education, and intervention

15. NUMBER OF PAGES

170

16. PRICE CODE**17. SECURITY CLASSIFICATION
OF REPORT**

Unclassified

**18. SECURITY CLASSIFICATION
OF THIS PAGE**

Unclassified

**19. SECURITY CLASSIFICATION
OF ABSTRACT**

Unclassified

20. LIMITATION OF ABSTRACT

Unlimited

TABLE OF CONTENTS

1. Cover.....1

2. SF 298.....2

3. Introduction.....4

4. Body.....4

5. Key Research Accomplishments.....6

6. Reportable Outcomes.....6

7. Conclusions.....7

8. References.....7

9. Appendices.....7

3. INTRODUCTION

The proposed study will utilize a group, randomized controlled study design to evaluate the effectiveness interventions and to: (1) prevent sexually transmitted infections (STIs), unintended pregnancies (UIPs), alcohol and other substance misuse, and exposure to or involvement with sexual violence among Marine Corps recruits and Army advance individual training (AIT) trainees; (2) reduce participants' risk for STIs, UIPs, alcohol and other substance misuse, and exposure to or involvement with sexual violence by (a) decreasing gaps in knowledge and misperceptions about risk and prevention, (b) increasing motivation to change risk behaviors, (c) building effective skills to engage in health promoting behaviors, and (d) decreasing sexual risk behavior; and. (3) determine the best strategy for educating participants about the sensitive health matters such as STIs, UIPs, alcohol and other substance misuse, and exposure to or involvement with sexual violence. Specifically, we will determine whether it is more effective to prevent these adverse health outcomes by educating males and females in an integrated setting (co-ed Army AIT trainees) or to educate them separately (Marine Corps male and female recruits). Additionally, all participants will complete self-administered questionnaires and will be screened for STIs (*C. trachomatis* and *N. gonorrhoeae*) at baseline and 12 months post-intervention and will be screened for pregnancy/UIP at follow-up.

4. BODY

This year was spent seeking Institutional Review Board (IRB) approval to conduct elicitation research at each participating performance site, including our home institution, University of California, San Francisco (UCSF), the Naval Health Research Center (NHRC), San Diego, CA to conduct research at the Marine Corps Recruiting Depot, Parris Island, SC, and the Brook Army Medical Center (BAMC), San Antonio, TX to conduct research at Fort Sam Houston, San Antonio, TX. In addition, we have submitted an application to the Human Subjects Research Review Board (HSRRB) at Fort Detrick, MD, as required.

To date, we have IRB approval from all performance site institutions. However, we have not obtained IRB approval from the HSRRB. We were recently requested by the HSRRB (January 20, 2005) to make additional revisions to our already approved protocols. These requested revisions are currently underway. See Appendices for copies of all approved IRB protocols.

The following summarizes progress on approved Statement of Work activities.

STATEMENT OF WORK (SOW)

1. Brief commanding officers at each participating site and enlist the support of the preventive medicine and medical community at each of the participating commands.

To date, we have briefed and enlisted the support of individuals at the following locations:

- (1) **Fort Bragg, NC:** MAJ Lolita Burrell (then CPT (P), Richard Carr, and Crystal Ross. MAJ Burrell will play a major role in all operational and scientific aspects of the study. We have monthly conference calls with her and her staff to discuss all aspects of the study.
 - (2) **Fort Monroe VA:** COL James Jolissaint, Command Surgeon, US Army TRADOC, and Dr. Carole van Aalten, Risk Reduction Manager. To date, we have had three conference calls with Col Jolissaint and Dr. van Aalten. COL Jolissaint has played a key role in assisting us in identifying Fort Sam Houston as a participating performance site. He and Dr. van Aalten are serving as Army operational consultants for the project.
 - (3) **Fort Sam Houston, TX:** Col Maureen Coleman, AMEDDCS, the Commanding Officer of the 32nd Medical Battalion, MAJ Beverly Jefferson, MAJ Chad Nelson, CPT David Glen, CPT Jennifer Jablin, and LTC Caron Wilbur. COL Coleman retired last fall. LTC Wilbur is now our point of contact. She has subsequently been named as a site investigator by the BAMC IRB. LTC Wilbur will assist in setting up focus group discussions and all operational and scientific aspects of the study that pertains to Fort Sam Houston.
 - (4) **MCRD, SC:** COL Biszak, the Commanding Officer of MCRD was briefed by his Executive Officer LTC Daniel Elzie. LTC Elzie along with MAJ Neal Pugliese, MAJ John Holbrook, MAJ Diana Staneszewski, MAJ Eric Junger, COL Johnson (Commanding Officer of 4th Battalion), MAJ Carolyn Bird (Executive Officer of the 4th Battalion) were briefed on the proposed study. MAJ Pugliese and MAJ Carolyn Bird are our points of contact.
 - (5) **Naval Hospital, Beaufort, SC:** CAPT James Hoffower (Commanding Officer) and CAPT H. John Gerhard (Executive Officer) have been briefed regarding the goals and objectives of the proposed research.
2. Conduct elicitation research (focus groups and interviews) to develop: (1) separate gender- and branch-specific interventions to reduce health damaging behaviors associated with STIs, unplanned pregnancies, alcohol and other substance misuse, and sexual violence; and (2) pre- and post-intervention self-administered questionnaires to assess knowledge, attitudes, and beliefs, and behaviors of the target groups.
 - (1) This task has not been completed as we are still seeking final IRB approval from the HSRRB.
 3. Develop interventions specifically for Army male and female recruits at Fort Jackson (co-ed intervention) and Marine Corps male recruits (Parris Island MCRD). We will adapt our already evaluated intervention for Marine Corps female recruits by adding a component on sexual violence.

- (1) Although we have not had the opportunity to conduct the elicitation phase of the study to assist in the development of the intervention-specific research, preliminary work is ongoing. Specifically, we are in the process of conducting extensive literature reviews to examine effective health interventions related to STIs, UIPs, alcohol and other substance misuse, and sexual violence.
- (2) We have also made contact with other research investigators to obtain curricula from interventions that have proven to be successful. Information obtained as a result of this preliminary research will be used to inform the development of the proposed interventions.
- (3) We have also had a number of conversations with the filmmaker from Paradise Video to begin to discuss the development of the videos that will be used in conjunction with other intervention material.

The following SOW tasks have not been completed, as they are contingent upon activities yet to be accomplished as described above.

4. Pilot-test the interventions, self-administered questionnaires, and the biological specimen collection protocol for feasibility in each command.
5. Implement the gender- and branch-specific interventions at each command.
6. Conduct 12-month follow-ups of military personnel participating in the interventions.
7. Evaluate the effectiveness of each intervention and compare differences across interventions on key outcomes of interest, including (1) STIs, (2) UIPs, (3) alcohol and other substance misuse, and (4) sexual violence.
8. Disseminate study findings through: (1) briefs given to participating military commands; (2) presentations at military-specific preventive medicine meetings as well as annual scientific meetings, and (3) publications submitted to scientific journals.

5. KEY RESEARCH ACCOMPLISHMENTS TO DATE

The key research accomplishments to date are described above. Namely, we have IRB approval from our home institution (UCSF), and local IRB approval from BAMC for research with Army AIT trainees at Fort Sam Houston and NHRC for research with Marine Corps recruits. We are awaiting final approval from the HSRRB, Fort Detrick.

6. REPORTABLE OUTCOMES

There are no reportable outcomes to date.

PROPOSED PROJECT ACTIVITIES:

Our plans for the coming year include SOW activities outlined in items 2-5 above. Specifically, we plan to conduct elicitation research, develop the proposed intervention curricula, and pilot-test the interventions, self-administered questionnaires, and the biological specimen collection protocol for feasibility in each command. Moreover, we will continue to brief and update the officers at each of the participating commands.

7. CONCLUSIONS

There are no scientific conclusions that can be made at this time.

8. REFERENCES

We currently have no references to report.

9. APPENDICES

Appendix 1: BAMC approved protocol (39 pages)

Appendix 2: NHRC approved protocol (87 pages)

Appendix 3: UCSF approval letters (2 pages)

Appendix 4: Summary of Effective Interventions

A. HIV STI Prevention Programs (17 pages)

B. Sexual Violence Prevention Programs (13 pages)

C. Substance Abuse Prevention Programs (8 pages)

BAMC/WHMC Approved Protocol

**BAMC/WHMC
PROTOCOL FOR CLINICAL INVESTIGATION – HUMAN**

1.0 Title:

Preventing Health Damaging Behaviors in Army and Marine Corps Recruits

2.0 Principal Investigator (PI):

Cherrie B. Boyer, PhD

Professor

Department of Pediatrics, Division of Adolescent Medicine

University of California, San Francisco

3333 California Street, Suite 245, Box 0503

San Francisco, CA 94143-0503

Telephone: 415.514-3672 (Assistant Susan Pierce)

Facsimile: 415.475-6106

Email: boyer@itsa.ucsf.edu

2.1 BAMC on-site Principal Investigator:

MAJ Caron Wilbur, Army Nurse Corps, BAMC on-site Principal Investigator

Chief Program Management and Proponency

Department of Combat Medic Training

ATTN: MCCS-ACG

Bldg 1373, W.W. White Road

Fort Sam Houston, TX 78234

Telephone: 210-221-3118

Facsimile: 210-221-3120

Email: caron.wilbur@amedd.army.mil

2.2 Associate Investigators (AI):

Mary-Ann Shafer, MD, Co-Principal Investigator,

Professor

Department of Pediatrics, Division of Adolescent Medicine

University of California, San Francisco

3333 California Street, Suite 245, Box 0503

San Francisco, CA 94143-0503

Telephone: 415.514-3672 (Assistant Susan Pierce)

Facsimile: 415.475-6106

Email: shafer@itsa.ucsf.edu

Julius Schachter, PhD, Co-Investigator, University of California, San Francisco

Professor of Laboratory Medicine

Department of Laboratory Medicine

School of Medicine

Director, World Health Organization Collaborating Center for Reference and Research on Chlamydia

1001 Potrero Avenue, Building 30, Room 416
San Francisco General Hospital
University of California, San Francisco
San Francisco, CA 94110
Telephone: (415) 824-5115
Facsimile: (415) 821-8945
Email: jsch@itsa.ucsf.edu

CPT Lolita Burrell, Ph.D., Medical Service Corps, Co-Investigator
USARIEM/WAMC Medical Research facility
Attn: MCXC-R, Womack Army Medical Center
Bldg 4-2817, Reilly Road
Fort Bragg, NC 28310
Telephone: (910) 907-8797
Facsimile: (910) 907-7870
Email: Lolita.burrell@na.amedd.army.mil

See Appendix I for a copy of the Investigators' curricula vitae.

3.0 Location(s):

Fort Sam Houston, Texas
Marine Corps Recruiting Depot (MCRD), Parris Island, SC

4.0 Research Plan (*Complete sections 4.1 - 4.10 below*)

4.1 Purpose:

The overall purpose of the proposed research is to: (1) prevent sexually transmitted infections (STIs), unintended pregnancies (UIPs), alcohol and other substance misuse, and exposure to or involvement with sexual harassment and sexual violence in military personnel; (2) reduce military personnel's risk for STIs, UIPs, alcohol and other substance misuse, and exposure to or involvement with sexual harassment and sexual violence by: (a) decreasing gaps in knowledge and misperceptions about risk and prevention, (b) increasing motivation to change risk behaviors, (c) building effective skills to engage in health promoting behaviors, and (d) decreasing sexual risk behavior; and, (3) determine the best strategy for educating military personnel about sensitive health matters such as STIs, UIPs, alcohol and other substance misuse, and exposure to or involvement with sexual harassment and sexual violence. Using the current structure in which the Army and Marine Corps train their recruits and young enlisted personnel, we will determine whether it is more efficacious to prevent these adverse health outcomes by educating males and females in an integrated setting (co-ed military trainees) or to educate them separately (Marine Corps male and female recruits).

Given that the proposed interventions will be developed specifically for Army and Marine Corps recruits and young enlisted trainees, we will first conduct focus groups to collect information to help guide the development of the interventions and the pre- and post-intervention questionnaires that will be used to evaluate the effectiveness of the interventions (i.e., elicitation research phase). As such, we are seeking approval only for the elicitation phase of the study at this time. This elicitation phase will

include focus group discussions with Army trainees, Marine Corps recruits, and other active duty personnel.

4.2 Hypotheses/Research Questions: The elicitation phase is not designed for hypothesis testing. Rather the focus groups will allow for examination of specific themes and/or categories of information that will be used in the development of the interventions.

4.3 Significance:

Building on our previous military research, we will expand and extend our interventions to further enhance the health, well-being, and readiness of our young troops. We plan to evaluate a state-of-the-science cognitive-behavioral, skills-building intervention to prevent and reduce recruits' risk for STIs, UIPs, alcohol and other substance misuse, and exposure to or involvement with sexual harassment and sexual violence. Given current trends for integrated military training of males and females, this research also seeks to establish the best training practices for educating young troops about sensitive and critical health issues that impact military performance and readiness. Currently, there is little empirical evidence which address the issue of best health education practice, especially among young adults. This research will have direct application for health promotion and disease prevention education strategies designed to reach military men and women early in their careers.

4.4 Military Relevance:

Providing health promotion and disease prevention education strategies to military men and women early in their careers will benefit the military by reducing the healthcare costs associated with sexually transmitted infections and their sequelae of ectopic pregnancy, tubal infertility, pelvic inflammatory disease, and increased risk of exposure to the human immunodeficiency virus (HIV). In addition, health promotion and disease prevention education has the potential of reducing the financial burdens associated with substance abuse, sexual harassment, sexual violence, and unintended pregnancies. Additional cost savings may occur in the form of reduced attrition rates that may be associated with these health issues. This research will also benefit the military not only by promoting health readiness but also by promoting mission readiness. Mission readiness may be compromised through factors such as lost duty days and decreased physical fitness that may occur as outcomes of decreased health readiness.

4.5 Background/ Review of Literature:

The health damaging behaviors of young military recruits are reflections of the health problems facing all young people in the United States. Military life presents additional opportunities and challenges that may both protect and place its young troops at risk for engaging in health damaging behaviors. Preventable challenges for maintaining a healthy armed force include the high rates of sexually STIs, UIPs, misuse of alcohol and other substances as well as the presence of sexual harassment and sexual violence within our young troops. The common thread through these negative health outcomes is volitional behavior. Such behaviors not only result in illness or injury, but may also negatively impact performance of military duties and thereby threaten military readiness. Nationally, the military has taken leadership in setting standards and policies regarding professional behavior and universal health care not only for reproductive health, but also for preventing misuse of alcohol and other substances and for eliminating sexual harassment and sexual violence. However, among our young troops, STIs remain epidemic, more than two-thirds of pregnancies are unintended, alcohol misuse is prevalent,

sexual harassment, and sexual violence remains a problem. Therefore, a gap exists between expected and actual health behaviors and outcomes that may negatively affect military performance and readiness. Promising results from our prevention interventions targeting Marine Corps males prior to deployment¹ and Marine Corps female recruits² show reductions in adverse health behaviors and outcomes, including alcohol misuse, risky sexual behaviors, UIPs, and STIs.

Sexually Transmitted Infections

STIs, the most common infections of young adults, are associated with major preventable health morbidity especially in women (e.g., PID, ectopic pregnancy, infertility) and their offspring (e.g., congenital infection complications). As with the population at-large, STIs are also very common among young military recruits and active duty personnel. Screening rates using nucleic acid amplification tests (NAATs) applied to urine of Army female recruits yielded a chlamydia rate of 9%.³ Our group's study of STI screening of Marine Corps female recruits yield an overall STI rate of 14% (11% for chlamydia, 2% for gonorrhea, 1% for trichomonas) using urine, endocervical, and self-administered vaginal swab specimens.^{4,5} These rates of chlamydia for Army and Marine Corps female recruits are twice that reported for similar-aged women attending family planning clinics⁶. STIs in active duty personnel reveal similarly high rates. For example, in a group of active duty Navy women, chlamydia prevalence was 7% using NAATs applied to urine. Among Army male recruits, chlamydia was 5% and gonorrhea was detected in 0.6% using NAATs applied to urine.⁷ Among active duty Marine Corps men on deployment in Okinawa, Japan who were screened by NAATs urine tests, chlamydia was detected in 5% of the sample.⁸ Among male Marines screened just prior to a deployment to the western Pacific, 4% had chlamydia with no gonorrhea detected.⁹ Our group has further defined the prevalence of the syndrome bacterial vaginosis (BV) among Marine Corps female recruits (27%), which has been related to premature births in infected women.¹⁰ Control of STIs, especially through chlamydial screening of asymptomatic women, has been shown by our group and others (military) to be cost-effective.^{11,12}

Unintended Pregnancy

UIPs in young military women place the woman, her family, and the military potentially at risk for not accomplishing their respective missions. There is evidence to show that pregnancy outcomes for military women fare worse than comparable civilian women showing more premature births, and other complications.^{13,14} Furthermore, there is the constant concern of any pregnancy, but especially ectopic pregnancy, occurring while military women are on deployment. Like civilian women, most pregnancies are unintended (55%).¹⁵ Data from our recent study of Marine Corps female recruits who were followed during their first year of military service showed an overall pregnancy rate of 18% of which two-thirds were unintended (unpublished data). Prevention of both STI acquisition and unintended pregnancy in young military men and women is necessary to assure the health of young military population and to ensure the readiness mission of our armed forces.

Alcohol and Other Substance Use and Misuse

The high prevalence of alcohol and other substance use in young adults poses a significant threat to their health and well-being. National data indicate that 44% of U.S. adults (ages 18 and over) report current drinking, that is, consuming at least 12 drinks of alcohol in the proceeding year. The rate of current alcohol use among adults is highest (64%) in the 18-25 age group.¹⁶ Similarly, 14% of persons

aged 18-25 reported heavy alcohol use (five or more drinks on one occasion at least once a week in the prior month), with 18% occurring in persons aged 21 years.¹⁶ As in the civilian population, rates of alcohol in military personnel are high, although there have been documented decreases in illicit drug use over the last two decades.¹⁷ Among the 16,000 military personnel responding to the 1995 Department of Defense (DOD) survey of health-related behaviors, rates of heavy alcohol use was documented among 5% of women and 19% of men. Similarly, illicit drug use was 5% for women and 7% for men.¹⁷ Less is known about military recruits. However, one study of 2,002 Naval recruits indicate that 75% of recruits consumed alcohol in the year before enlistment, and 26% engaged in heavy drinking, and 31% reported other substance use. Our recent research among Marine Corps female recruits indicates that in the month prior to enlistment, 67% reported alcohol use and 6% reported substance use, and 57% engaged in sexual intercourse under the influence of alcohol and/or drugs.⁴ Taken together these data suggest the need for interventions to reduce the misuse of alcohol and other substances among military recruits that might later interfere with performance of their military duties and ultimately military readiness.

Sexual Harassment and Sexual Violence

Research has consistently revealed high rates of sexual harassment and sexual violence among military personnel.¹⁸⁻²¹ For example, one study of Army soldiers found that one-fifth (23%) of the women reported a history of rape, and 51% of women and 7% of men reported any sexual assault,¹⁸ of which a majority occurred before the soldiers entered the military, primarily during childhood. The 1995 DOD-wide survey showed that 55% of women and 14% of men experienced at least one incident of unwanted sexual attention during the preceding year. Although these rates represent a decline from previous years, the decline in the Army was noted to be less.¹⁹ Among Army women, this research found that 61% had experienced sexual harassment while 18% experienced sexual coercion, and 5% experienced sexual assault.¹⁹ Additionally, a national cross-sectional survey of 558 women veterans who served in the military during Vietnam and subsequent eras was conducted to assess military environmental factors associated with rape during military service. This research indicates that rape was reported in 28% of the women, with consistent rates found across all the time periods.²⁰ Military environmental factors that were associated with increased likelihood of rape included sexual harassment allowed by officers ($p < 0.0001$), unwanted sexual advances while on-duty ($p < 0.00001$), and while in sleeping quarters ($p < 0.0001$). Overall, these data indicate that there is a gap between the military's "zero tolerance" and the ongoing problems of sexual harassment and sexual violence in the armed services. Therefore, sexual harassment and sexual violence remain an important health risk to both military women and men and their families, suggesting that early interventions are necessary to decrease negative health outcomes associated with sexual violence and to provide an environment where both men and women feel respected and safe, thereby protecting the cohesion that is necessary to fulfill the overall mission of the DOD.

Interventions to Prevent Health Damaging Behaviors

Research has shown that STI and HIV prevention interventions that are based on cognitive-behavioral principles are effective strategies for building skills and/or modifying behaviors associated with the acquisition of STI and HIV infections in various populations.²²⁻²⁶ However, none of the studies involved military personnel. However, our recent interventions based on cognitive-behavioral skills-building principles implemented in young Marine Corps males prior to deployment¹ and Marine Corps female recruits² have shown promise for reducing health damaging behaviors and negative health

outcomes and their sequelae in this young population. Building on our groups' research and the basic research by others, which identify correlates of STIs,^{4,27} unplanned pregnancies⁸, alcohol use,^{9, 17, 28} and sexual harassment and sexual violence^{19, 20} in military personnel, we plan to develop and evaluate interventions that will target these key factors. Importantly, the proposed interventions will capitalize on military-specific factors that are both health promoting and health damaging. We will target recruits for a number of important reasons: (1) the high rates of STIs among military recruits; (2) many recruits enter military service with a history of alcohol and other substance use; and (3) many women and some men come to the military with a history of exposure to sexual violence. Furthermore, since previous research suggests that gender-specific interventions are key to successful STI and HIV prevention,^{29, 30} we will also examine whether an intervention that gender-integrated versus interventions that are gender-separate are more effective in preventing STIs, UIPs, misuse of alcohol and other substances, sexual harassment, and sexual violence. The manner in which the Army (co-ed) and the Marine Corps (gender separate) train their recruits and young enlisted personnel provides a unique opportunity to assess this important health education question.

The proposed intervention will build on our previous work and will be guided by the Information, Motivation, and Behavioral Skills (IMB) model.³¹ The IMB posits that information, motivation, and behavioral skills are the primary determinants of AIDS-preventive behavior. Specifically, the model asserts that information regarding the transmission and prevention of AIDS is a necessary prerequisite of risk-reduction behavior. Motivation to change risk behaviors is a determinant of prevention and affects whether one acts on one's knowledge regarding the transmission and prevention of AIDS. The IMB also asserts that motivation to engage in preventive behaviors is a function of one's attitudes toward the behavior and of perceived norms regarding preventive behaviors. Other critical factors hypothesized to influence motivation to engage in AIDS-preventive behaviors are perceived vulnerability to AIDS and intention to engage in preventive behaviors regarding AIDS. Behavioral skills for engaging in specific preventive behaviors are a third determinant of AIDS-preventive behaviors and affect whether even a knowledgeable, highly motivated person will be able to change his or her behavior to prevent negative health outcomes. Requisite skills to engage in preventive behaviors include the ability to effectively communicate with one's sexual partner about safer sex, to refuse to engage in unsafe sexual practices, and to properly use condoms. In addition to possessing these skills, individuals who practice preventive skills are presumed to have a strong self-belief (self-efficacy) in their ability to practice these preventive behavioral skills. We will extend this model to assess STIs, UIPs, alcohol and substance use, sexual harassment, and sexual violence.

4.6 Research Design and Methods:

a. Target Population.

Potential participants will include male and female Marine Corps recruits, military trainees, and other (junior enlisted) active duty military personnel who can provide information about the risks and/or prevention of STIs, UIPs, alcohol and other substance misuse, sexual harassment, and sexual violence within the military context. Participation will be voluntary. All potential participants will be fluent in English and able to provide written, informed consent. Our previous research and that of others show that adolescents are at increased risk for many of the health damaging behaviors and negative health outcomes that are the focus of this research.¹⁻²⁵ Therefore, it is important to include adolescents in this research.

b. Methods that will used to obtain sample.

Recruits/ Military trainees: For recruits and military trainees, we will ask for volunteers only within each training platoon or AIT class during a time in which they are already convened for training purposes. A script of points to be emphasized will be provided to drill instructors for recruits and class instructors for military trainees to introduce a member of our research team who will provide an overview of the study and to request volunteers to participate in the elicitation phase of the study (see Appendix 2 for the instructors' introduction script). Drs. Boyer or Shafer will provide a Brief on the overall study and will provide the participants with specific information on the elicitation phase of the study.

Non-training junior enlisted personnel: Junior enlisted personnel who are not in training will be invited to attend a brief to learn about the study through a flyer that will be provided to all Command-identified Unit Commanders (see Appendix 4 for a copy of the recruitment flyer). For individuals attending the Brief, Drs. Boyer or Shafer will provide an overview of the overall study and will provide the participants with specific information on the elicitation phase of the study.

c. Pregnant Subjects.

Since pregnant women are excluded from recruit training/AIT, none of the female recruits/ military trainees volunteering to participate in this phase of the study will be pregnant. Active duty women who are pregnant will not be excluded from participation in the focus groups.

d. Subject Identification.

For the elicitation phase of the study, there is some risk of the participants' loss of privacy. The participants' names and ranks will be known, but no other identifying information will be obtained. It is important to note that the participants' names will not be used in the focus group discussions or any of the transcribed materials. Data will be reported in the aggregate. If a direct quote is used in the description of the data, only the individual's gender and military rank will be identified as the author of the quote. Therefore, since no protected health information is being requested, HIPPA regulations do not apply for this study.

e. Description of the Recruitment Process.

The goal of the elicitation phase of this study is to conduct focus groups to develop: (1) separate gender- and branch-specific interventions to reduce health damaging behaviors associated with STIs, UIPs, alcohol and other substance misuse, sexual harassment, and sexual violence; and (2) pre- and post-intervention, self-administered, questionnaires to assess knowledge, attitudes, and beliefs, and behaviors of the target groups.

Recruiting recruits/ Military trainees: We will seek volunteers to participate in focus group discussions. For recruits and military trainees, we will ask for volunteers only within each training platoon or AIT class during a time in which they are already convened for training purposes. A script of points to be emphasized will be provided to drill instructors for recruits and class instructors for military trainees to introduce a member of our research team who will provide an overview of the study and to request volunteers to participate in the elicitation phase of the study (see Appendix 2 for the instructors' introductory script). Therefore, all recruits/trainees within the Command-identified

platoons/class that are eligible for participation will have an opportunity to learn about the study. As with our previous research, drill instructors or any other military personnel will not be present during study recruitment in order to avoid feelings of coercion or undue pressure. Recruitment and focus group participation will take place during regularly scheduled periods of training (see Appendix 3 for the recruitment script).

Recruiting non-training junior enlisted personnel: Junior enlisted personnel who are not in training will be invited to attend a brief to learn about the study through a flyer that will be provided to all Command-identified Unit Commanders (see Appendix 4 for a copy of the recruitment flyer). As with our previous research, no military personnel other than potential participants will be present during study recruitment in order to avoid feelings of coercion or undue pressure. Recruitment and focus group participation will take place during work hours at or near their places of work.

Based on our team's previous research experience in conducting sensitive health research with junior enlisted military personnel and recruits, our uniformed military colleagues (MAJ Wilbur and CPT Burrell) will not actively participate in recruiting and consenting participants or the collection of focus group data in order to decrease the likelihood that focus group participants will feel coerced in participating and to increase the likelihood that they will be as open and honest as possible when responding to focus group questions.

f. Description of the Consent Process.

Drs. Boyer and Shafer will provide a Brief (overview) of the overall goals and purpose of the study as well as the goals and purpose of the elicitation phase of the study. For recruits and military trainees, the Brief will be provided within each of the training platoons/class without drill instructors or other active duty personnel present. After the Brief, recruits and military trainees will be invited to participate in a two-hour focus group discussion that will take place at a later predetermined time. Based on our previous experience, we anticipate that most of the recruits and military trainees will want to participate, therefore, we will randomly select up to 7 individuals from each of the platoons/class who indicate their willingness to volunteer to participate in the focus groups (each recruit/ military trainee will be given a number when they enter the Brief; 7 numbers will be chosen based on a random assignment table). These individuals will be asked to remain in the room after the Brief is over. At this point, these individuals will be given a copy of the Human Subjects Bill of Rights Statement and given an opportunity to read the informed consent statement, ask questions, and sign the consent statement. For active duty (non-training) military personnel, flyers inviting them to come hear a Brief about the study will be posted in and around the Command-identified units. Briefs will be provided only to those individuals who choose to attend the briefs. After the Briefs are completed, up to 7 individuals from each unit will be invited to participate in the focus groups as described above (see Appendix 5 for a copy of the informed consent forms; also see Appendix 6 for the University of California, San Francisco's Committee on Human Research this committee's letter of approval for conducting the elicitation phase of this study).

g. Subject Assignment.

We will convene both gender-separate and co-ed groups since interventions will be conducted with gender-separate groups (Marines) and in co-ed groups (Army). Training platoons for the Marine Corps are separated by gender, therefore, focus group discussions for Marine Corps participants will be

gender specific only. However, since Army ATI is co-ed, we will determine which class will participate in same-gender discussions and which class will participate in co-ed discussions using a random assignment table of odd and even numbers. For example, all classes will be listed in a random order and assigned an odd or even number a priori. All even-numbered classes will be assigned to co-ed discussions and all odd-numbered platoons will be assigned to separate same-gendered discussions. Specifically, we will conduct three separate focus groups with female Marine Corps recruits and three separate focus groups with male Marine Corps recruits (for a total of six focus groups among Marine Corps recruits). For military trainees, we will conduct two co-ed focus groups, two focus groups with males, and two focus groups with females (for a total of six focus groups among military trainees). Non-training active duty participants will be recruited within their work units. As described, only individuals who attend the Briefs and who agree to participate in the focus groups discussions will be assigned a number and randomly assigned to co-ed and same-gender focus groups using a random assignment table. For junior enlisted Army personnel there will be two male and two female group and two co-ed groups (for a total of six Army junior enlisted groups). For junior enlisted Marine Corps personnel there will be two male and two female groups and two co-ed groups from MCRD (for a total of six Marine Corps junior enlisted groups). Overall there will be 12 focus groups for junior enlisted (non-recruit/ military) military personnel. As stated earlier, these groups will be conducted among individuals within the same ranks. Each focus group discussion will consist of 5-7 participants each, which has been identified as an ideal number for such group discussion.²⁴ All focus group discussions will be conducted by Drs. Boyer and Shafer. All information will be audio recorded and will be transcribed by an independent research group who specializes in qualitative data transcription. Once these data are transcribed, the audio tapes will be destroyed. The transcripts will be analyzed and used solely for development of the interventions and pre- and post-intervention questionnaires. The transcripts will not contain any personal identifying information of the participants. Only demographic information describing the source of information will be included. Such information will include the participants' gender, military branch, and whether they are a recruit/ military trainee or junior enlisted personnel. This information will help to provide a contextual framework for the data reported.

4.7 Source of Research Material:

Source of Research Material	Standard Care?
<i>Semi-structured group interview</i>	<i>N</i>

4.8 Instrumentation (as applicable):

The focus group will involve semi-structured group interviews. See Appendix 7 for copies of focus group questions for Army ATI trainees and Marine Corps recruits (male, female, and co-ed) and other military personnel (male, female, and co-ed).

a. Labeling of the Instrument.

The focus group questionnaires will be used by Drs. Boyer and Shafer to facilitate the group discussion only and will not be seen by the group participants. Each questionnaire contains the title of the study as well as title identifying the group to be targeted in the discussion.

b. Objectives of the Instrument.

The purpose of the focus group questionnaires are to assist in the development of the interventions as well as the pre- and post-intervention questionnaires that will be used to evaluate the interventions.

c. Validity and Reliability of the Instruments.

These instruments are used for elicitation purposes and for the development of the intervention and evaluation instruments as such they have not been tested for validity or reliability.

d. Instructions.

The facilitators will provide verbal instructions and will verbally ask each of the questions in the focus groups.

4.9 Inclusion/exclusion criteria:

All potential participants will be fluent in English and able to provide written, informed consent. Our previous research and that of others show that adolescents are at increased risk for many of the health damaging behaviors and negative health outcomes that are the focus of this research.¹²³ Therefore, it is important to include adolescents in this research. Since pregnant women are excluded from recruit training/AIT, none of the female these volunteers will be pregnant. Active duty women who are pregnant will not be excluded from participation in the study.

4.10 Number of Subjects: State only what is applicable.

TOTAL NUMBER OF SUBJECTS (study-wide): 24 focus groups with 5-7 per group = up to 168 study participants.

Number of participants planned for BAMC: 12 focus groups with 5-7 per group = up to 84 study participants.

Number of participants planned for Marine Corps Recruiting Depot (MCRD), Parris Island, SC: 12 focus groups with 5-7 per group = up to 84 study participants.

1. Co-ed junior enlisted Soldiers- 2 groups
2. Female junior enlisted Soldiers- 2 groups
3. Male junior enlisted Soldiers- 2 groups
4. Co-ed Army military trainees- 2 groups
5. Female Army military trainees- 2 groups
6. Male Army military trainees- 2 groups
7. Co-ed junior enlisted Marines- 2 groups
8. Female junior enlisted Marines- 2 groups
9. Male junior enlisted Marines- 2 groups
10. Female Marine recruits- 3 groups
11. Male Marine recruits- 3 groups

5.0 Human Subject Protection (Complete sections 5.1 - 5.6 below)

5.1 Recruitment:

The goal of the elicitation phase of this study is to conduct focus groups to develop: (1) separate gender- and branch-specific interventions to reduce health damaging behaviors associated with STIs, UIPs, alcohol and other substance misuse, and sexual harassment and sexual violence; and (2) pre- and post-intervention, self-administered, questionnaires to assess knowledge, attitudes, and beliefs, and behaviors of the target groups. For this phase of the study, we will seek volunteers to participate in focus group discussions. For recruits and military trainees, we will ask for volunteers within each Command-identified training platoon/class at both Army and Marine Corps training facilities after a Brief of the study is provided. Therefore, all recruits and military trainees will have an opportunity to learn about the study. As with our previous research, drill instructors or any other military personnel will not be present during study recruitment (see section 4.6.e above for our rationale). Junior enlisted personnel will be asked by members of the research team to voluntarily agree to participate in focus group discussions after hearing a Brief about the goals and purpose of the study. These individuals will be recruited from a group of volunteers who attended the Brief and who indicated a willingness to participate in the focus groups. Focus groups will be held within ranks to ensure that all participants feel comfortable sharing their ideas and views.

Drs. Boyer, Shafer, and/or their trained civilian research assistant(s) will provide a Brief (overview) of the overall goals and purpose of the study as well as the goals and purpose of the elicitation phase of the study. For recruits and military trainees, the Brief will be provided within each of the training platoons/class without instructors or other active duty personnel present. After the Brief, recruits and military trainees will be invited to participate in a two-hour focus group discussion that will take place at a later predetermined time. Based on our previous experience, we anticipate that most of the recruits and military trainees will want to participate, therefore, we will randomly select up to 7 individuals from each platoon/class who indicate their willingness to volunteer to participate in the focus groups (each recruit/trainee will be given a number when they enter the Brief; 7 numbers will be chosen based on a random assignment table). These individuals will be asked to remain in the room after the Brief is over. At this point, these individuals will be given an opportunity to read the informed consent statement, ask questions, and sign the consent statement. They will also be given the Human Subjects Bill of Rights Statement. For active duty military personnel, Briefs will be provided in groups who voluntarily attend a Brief to hear about the study. After the Briefs are completed, up to 7 individuals from each Unit will be invited to participate in the focus groups as described above.

5.2 Benefits:

The participants in the focus group discussions may not directly benefit from participation in the focus groups. However, a potential benefit to the participants is the personal satisfaction in contributing information that will help in the development of interventions to prevent STIs, UIPs, alcohol and other substance misuse, sexual harassment, and sexual violence in future cohorts of Army and Marine Corps recruits and junior enlisted personnel. Development of interventions to reduce negative health outcomes may reduce the risk and incidence of health outcomes in military personnel, will enhance military readiness, and may benefit society at-large by reducing the future health consequences and health care cost associated with these negative health outcomes.

5.3 Risks:

The risk of participating in focus group discussions are expected to be minimal. Since some of the questions will focus on risks and prevention of STDs, UIPs, alcohol and other substance misuse, sexual harassment, and sexual violence some of the questions may be embarrassing for some of the participants, every effort will be made to minimize this possible discomfort.

5.4 Safeguards for Protecting Subjects:

We will minimize potential risks for participants by first informing them that they are free to not respond to any questions that make them feel uncomfortable. Also, we will inform the participants that information discussed in the focus groups must be held in the strictest of confidence, that is, they must not share any information with anyone outside the group. It is important to note that the general purpose of the elicitation phase is to gather information that will assist in the development of pre- and post-intervention questionnaires as well as the actual interventions to reduce health damaging behaviors targeted in this research: STIs, UIPs, alcohol and other substance misuse, sexual harassment, and sexual violence. As such, participants are encouraged to describe their general perceptions of issues related to these factors and do not necessarily have to disclose information of their specific behaviors. If, in the event that any focus group participants show signs of or report psychological discomfort or distress during or immediately following the discussion, Drs. Boyer or Shafer will inform his/her drill instructor, class instructor or unit supervisor with request for referral for immediate care to a base psychologist or Chaplain who are tasked with caring for the mental health of recruits/ military trainees, and active duty personnel. Lastly, military personnel who are not participating in the research will not be present during the focus group discussions, as described above. To address the concern about participants revealing their sexual orientation, specific instructions will be given to participants to not disclose information about their sexual activity or sexual orientation, since the military has strict policies on not disclosing such information. In our 14 years of working with military personnel around these sensitive issues, we have gained the trust of our participants and have not had a negative or adverse event. We have gained the reputation of civilians with interests and expertise in developing health-related programs that is created specifically for the military with input from the military.

a. Serious or unexpected adverse events.

No serious or unexpected adverse events are anticipated during the elicitation phase of the study.

b. Include a definition of what constitutes an adverse event in the study.

No serious or unexpected adverse events are anticipated during the elicitation phase of the study as we will not ask participants to disclose any personal health or behavioral information.

c. Agencies or Offices to be Notified in the Event of a Serious and Unexpected Adverse Event.

Adverse experiences that are both serious and unexpected will be immediately reported by telephone to the USAMRMC, Deputy for Regulatory Compliance and Quality (301.619.2165) and send information by facsimile to (301.619.7803). A written report will follow the initial telephone call within 3 working days to the U.S. Army Medical Research and Materiel Command, ATTN: MCMR-RCQ, 504 Scott Street, Fort Detrick, Maryland 21702. In addition, any adverse experiences will be reported in writing to all Institutional Review Boards which is concerned with the protection of volunteers in research projects immediately by telephone and in writing within 3 working days of the event (these include: the Committee on Human Research, Box 0962, University of California, San Francisco/San Francisco, CA

94143; BAMC IRB Dept Clinical Investigation MCHE-CI, Brooke Army Medical Center, 3400 Rawley E. Chambers Ave, Ste. A., Fort Sam Houston, TX 78234-6315; and the IRB Naval Health Research Center, P.O. Box 85122 San Diego, CA 92186-5122).

5.5 Risk: Benefit Assessment:

The benefits of the elicitation phase of the study outweigh the risks. The risks are minimal and the benefits of developing an effective intervention could potentially lead to a lower prevalence/incidence of STIs, UIPs, alcohol and other substance misuse, sexual harassment, and sexual violence in future cohorts of Marine Corps recruits/military trainees, and other military personnel as they proceed through their military careers and their lives.

5.6 Alternatives:

An alternative to participation in this research is non-participation. Participation is strictly voluntary.

6.0 Data Analysis:

Focus group data will be analyzed using simple content analyses as described by Krueger.²⁴ All focus groups will be audio taped. Tapes will be transcribed by an external (independent) research group with experience in transcribing focus group and interview tapes. Transcripts will be analyzed using Nud*ist version N6 software. Drs. Boyer and Shafer, MAJ Wilbur and CPT Burrell along with Ms. Friedman will review the transcripts that will be organized by question across groups (both within and across military branches) to compare and contrast all findings. Attention will be placed on identifying themes or patterns across the groups as well as themes that relate to respondents with similar demographic characteristics (e.g., gender, rank). After this is completed, we will further summarize and synthesize the transcribed data using the Nud*ist software. These data will then be used in the interventions' development phase, as well as in the development of pre- and post-intervention questionnaires.

7.0 Sample size estimation/power analysis (if applicable).

No hypothesis testing will occur during the elicitation phase of the study.

8.0 Duration of Study:

Approximate duration of the elicitation phase of the study: 2 years to include data collection, data analysis, publication/presentation of the data and protocol closure. The anticipated time it will take to complete the data collection of elicitation phase of the study (focus group discussions) is approximately three months from the start date. This will be dependent on each command's ability to schedule focus group discussions within the participating platoons/units. Thus we anticipate that the focus groups will take place between August 30, 2004-November 30, 2004. It is also important to note that these dates are highly dependent upon when we are able to obtain approval of the IRBs at BAMC and the Naval Health Research Center.

9.0 Funding:

This research is funded by the United States Army Medical Research and Materiel Command, Fort Detrick Maryland. The official award number is Wx81WH-04-1-0159.

10.0 Staff Monitor (for resident and fellow projects)

N/A

11.0 Research Assistant

Allison Friedman (CIV), Research Assistant, UCSF, Division of Adolescent Medicine

Ms. Friedman will serve primarily as an administrative research assistant to Drs. Boyer and Shafer to help facilitate the recruitment, consenting and focus group discussions. In addition, she will take primary responsibility for running the Nud*ist qualitative data software to summarize and synthesize the focus group data. She will be under the direct supervision of Drs. Boyer and Shafer.

12.0 Bibliography:

1. Boyer CB, Shafer MA, Shaffer RA, et al. Prevention of sexually transmitted diseases and HIV in young military men: evaluation of a cognitive-behavioral skills-building intervention. *Sexually Transmitted Diseases*. 2001;28:349-355.
2. Boyer CB, Shafer MA. Preventing STDs and unplanned pregnancies: a cognitive-behavioral intervention for young women entering the U.S. military. *Journal of Adolescent Health*. 2003;32(2):129.
3. Gaydos CA, Howell MR, Pare B, et al. *Chlamydia trachomatis* infections in female military recruits. *NEJM*. 1998;339:739-744.
4. Boyer CB, Shafer MA, Moncada J, Schachter J, Shaffer RA, Brodine SK. Sociodemographic, behavioral, and clinical factors associated with STDs in a national sample of women entering the US military. *ISSTD: Sexually Transmitted Infections*. 2001:241-246.
5. Shafer MA, Moncada J, Boyer CB, Betsinger K, Flinn SD, Schachter J. Comparing the FVU, self-collected vaginal swabs and endocervical specimens to detect *C. trachomatis* and *N. gonorrhoeae* using Nucleic Acid Amplification Tests. *Submitted*. 2003.
6. CDC. *Sexually Transmitted Disease Surveillance 2000*. Atlanta, GA: Division of Sexually Transmitted Diseases, National Center for HIV, STD and TB Prevention; 2001.
7. Cecil JA, Howell MR, Tawes JJ, Gaydos JC, McKee KT. Features of *C. trachomatis* and *N. gonorrhoeae* in male army recruits. *Journal of Infectious Diseases*. 2001;184:1216-1219.
8. Brodine SK, Shafer MA, Shaffer RA, et al. Asymptomatic sexually transmitted disease prevalence in four military populations: Application of DNA amplification assays for chlamydia and gonorrhea screening. *Journal of Infectious Diseases*. 1998;178:1202-1204.
9. Shafer MA, Boyer CB, Shaffer RA, Schachter J, Ito SI, Brodine SK. Correlates of STDs in a young male deployed military population. *Military Medicine*. 2002;167:496-500.
10. Yen S, Shafer MA, Moncada J, Campbell CJ, Flinn SD, Boyer CB. Prevalence of clinical correlates of bacterial vaginosis among sexually experienced and non-sexually experienced young women entering the military. *Submitted* 2003.
11. Shafer MA, Pantell R, Schachter J. Is the routine pelvic examination needed with the advent of urine-based screening for sexually transmitted diseases? *Archives of Pediatric and Adolescent Medicine*. 1999;153:119-125.
12. Howell MR, Gaydos JC, McKee KT, Quinn TC, Gaydos CA. Control of *Chlamydia trachomatis* infections in female army recruits: cost-effective screening and treatment in

- training cohorts to prevent pelvic inflammatory disease. *Sexually Transmitted Diseases*. 1999;26:519-526.
13. Magann EF, Nolan TE. Pregnancy outcome in an active-duty population. *Obstetrics and Gynecology*. 1992;79:157.
14. McNeary AM, Lomenick TS. Military duty: risk factor for preterm labor? *Military Medicine*. 2000;165:612-615.
15. Clark JB, Holt VL, Miser F. Unintended pregnancy among female soldiers presenting for prenatal care at Madigan Army Medical Center. *Military Medicine*. 1998;163:444-448.
16. United States Department of Health and Human Services. *Alcohol research & health: highlights from the tenth special report to Congress. Health risks and benefits of alcohol consumption*. vol 24. Washington, DC: U.S. Government Printing Office; 2000.
17. Bray RM, Fairbank JA, Marsden ME. Stress and substance use among military women and men. *American Journal of Drug and Alcohol Abuse*. 1999;25:239-256.
18. Martin L, Rosen LN, Durand DB, Stretch RH, Knudson KH. Prevalence and timing of sexual assaults in a sample of male and female U.S. Army soldiers. *Military Medicine*. 1998;163:213-216.
19. Martin L. Personality characteristics that increase vulnerability to sexual harassment among U.S. Army soldiers. *Military Medicine*. 2000;165:709-713.
20. Sadler AG, Booth BM, Cook BL, Doebbeling BN. Factors associated with women's risk of rape in the military environment. *American Journal of Industrial Medicine*. 2003;43:262-273.
21. Sadler AG, Booth BM, Nielson D, Doebbeling BN. Health-related consequences of physical and sexual violence: women in the military. *Obstetrics and Gynecology*. 2000;96:473-480.
22. Jemmott III JB, Jemmott LS, Fong GT. Abstinence and safer sex HIV risk-reduction interventions for African American adolescents: a randomized controlled trial. *Journal of the American Medical Association*. 1998;279:1529-1536.
23. National Institute of Mental Health. The NIMH multisite HIV prevention trial: reducing HIV sexual risk behavior. *Science*. 1998;280:1889-1894.
24. Shain RN, Piper JA, Newton ER, et al. A randomized controlled trial of a behavioral intervention to prevent sexually transmitted disease among minority women. *N Engl J Med*. 1999;340:93-100.
25. Boyer CB, Barrett DC, Peterman TA, Bolan G. STD and HIV risk in heterosexual adults attending a public STD clinic: evaluation of a randomized, controlled, behavioral risk reduction intervention trial. *AIDS*. 1997;11:359-367.
26. Boyer CB, Shafer MA, Tschann J. Evaluation of a knowledge and cognitive-behavioral skills building intervention to prevent STDs and HIV infection in high school students. *Adolescence*. 1997;32(125):25-42.
27. Jenkins RA, Jenkins PR, Nannis ED, McKee Jr KT, Temoshok LR. Correlates of human immunodeficiency virus infections to risk behavior in male attendees of a clinic for sexually transmitted disease. *Clin Infect Dis*. 2000;30:723-729.
28. Williams JO, Bell NS, Amoroso PJ. Drinking and other risk taking behaviors of enlisted male soldiers in the US Army. *Work*. 2002;18:141-150.
29. Ehrhardt AA, Exner TM. Prevention of sexual risk behavior for HIV infection with women. *AIDS*. 2000;14(Suppl 2):S53-58.
30. Wingood GM, DiClemente RJ. HIV sexual risk reduction interventions for women: a review.

American Journal of Preventive Medicine. 1996;12(3):209-217.

31. Fisher JD, Fisher WA, Williams SS, Malloy TE. Empirical tests of an Information- Motivation- Behavioral skills model of AIDS-preventive behavior with gay men and heterosexual university students. *Health Psychol*. 1994;13:238-250.

13.0 Support Services Required (Impact Statement/Letter of Support):

See Appendix 8 for a signed copy of this statement.

14.0 Use of Investigation Drugs: N/A

15.0 Use of Investigational Devices: N/A

16.0 Signature Section:

16.1 Principal Investigator

I am aware that I am not authorized to accept any funds or other form of compensation for conducting research. All subjects will be treated in compliance with all applicable organizational, service, DoD and Federal regulations, and all applicable FDA and HHS guidelines.

Cherrie B. Boyer, PhD Date of Protocol Submission: _____ (before approval)

16.2 BAMC on-site Principal Investigator

I am aware that I am not authorized to accept any funds or other form of compensation for conducting research. All subjects will be treated in compliance with all applicable organizational, service, DoD and Federal regulations, and all applicable FDA and HHS guidelines.

CARON WILBUR

Date _____

MAJ, AN

32D Medical Brigade, Associate Investigator (on-site PI)

16.3 PI's Service Chief (BAMC)

I have considered this protocol and am able to approve personnel and resource support. I understand that I will be the point of contact for correction of deficiencies should the principal investigator fail to meet the requirements agreed to in the Letter of Compliance.

MAUREEN COLEMAN
COL, MS
Commander, 32D Medical Brigade

Date _____

16.4 Scientific Merit Review:

This protocol has been reviewed and found to have sufficient scientific merit for consideration by the Institutional Review Board.

JENICE N. LONGFIELD
COL, MC
Chief, Dept Clinical Investigation

Date _____

Attachment 1. Scripts

INSTRUCTORS' INTRODUCTORY SCRIPT
(for Marine Corps Recruits and AIT Trainees)

Today, we have researchers from the University of California, San Francisco who will give you information on a new program they are developing specifically for the military. They are looking for volunteers to discuss some of the issues they will address in the program. They are here to tell you more about the program. Please give them your undivided attention.

RECRUITMENT SCRIPT

Good Morning (Afternoon). I am Dr. Boyer and this is my colleague(s) (state name(s) of colleague(s)). We are researchers from the University of California, San Francisco and we have been funded by the Department of Defense to address issues that concern of young Marines/soldiers including the risk of sexually transmitted diseases such as chlamydia and gonorrhea, unintended pregnancies (that is pregnancies that were not planned), alcohol use and abuse, and sexual harassment as well as sexual violence. We have been working on these very important health issues for over 20 years (for Dr. Shafer for nearly 30 years). However, over the last 12 years we have worked with young military recruits and junior enlisted military personnel to help prevent these health problems. Our main interest is prevention. We have developed videos and educational programs that were developed with the help of young men and women Marines and soldiers such as you. These materials have been well received because we developed them with the help and insight of those we hope that will benefit from the information provided in the programs.

The reason we are here today is to ask for volunteers to spend about two hours with us to help us better understand health issues such as STDs, alcohol use, and sexual harassment and sexual violence and other health concerns that young Marines/soldiers may have. This two-hour group discussion will take place (indicate time/location) during your regularly scheduled class period (for recruits/AIT trainees)/during the work-day (for other junior enlisted personnel). I want to emphasize that you are not obligated to participate, we are looking for volunteers. If you choose

not to participate, it will not have any impact (positive or negative) on your training (career for non-training personnel).

In the group discussion we will not use your names or any other information that may identify you. We will not ask about your personal behaviors. We are particularly interested in your views and opinions. There are no right or wrong answers, but rather differing points of view. By participating in this discussion you will have an opportunity to help shape the development of programs that may help young Marines/soldiers that will come behind you.

Sensitive topics will be discussed and may make some people feel uncomfortable. As stated earlier, it is important that you do not mention names of any of other person during the focus group discussion. It is also important that you do not reveal any personal information, as there is no guarantee that what you say will not be repeated outside this room by other participants.

Revealing confidential information could lead to embarrassment and possible disciplinary actions under the Uniform Code of Military Justice.

If you are interested, please give us one of the placards that contain the number given to you when you entered the room. We will randomly select up to seven individuals to participate in each discussion. Pizza and beverages will be served."

"Note: Pizza, soda, juice and water will be provided for all other participants. For Recruits, juice and water (and pizza) will be provided to recruits only if it is allowed by the Drill Instructors.

Appendix 5. Recruitment Flyer

**SEXUALLY TRANSMITTED DISEASES
SEXUAL HARASSMENT
ALCOHOL**

**THESE ARE ISSUES THAT CONFRONT
YOUNG ADULTS**

**You have an opportunity to discuss your point of view on
these issues and help to develop a program that will address
concerns of young soldiers.**

**Researchers from the University of California, San
Francisco will be giving a brief on a program they will
develop to address these important issues in the military.**

**THEY ARE LOOKING FOR VOLUNTEERS TO PARTICIPATE
IN A TWO-HOUR GROUP DISCUSSION THAT WILL TAKE
PLACE DURING WORK-HOURS
(PIZZA AND SODA WILL BE SERVED)**

**You have an opportunity to give your opinions and point of
view that will help in the development of this health
program.**

**If you are interested, come to a 15-minute brief (*add time and
location here*) to learn more about the program and more
about the group discussion.**

**SEXUALLY TRANSMITTED DISEASES
SEXUAL HARASSMENT
ALCOHOL**

**THESE ARE ISSUES THAT CONFRONT
YOUNG ADULTS**

You have an opportunity to discuss your point of view on these issues and help to develop a program that will address concerns of young Marines.

Researchers from the University of California, San Francisco will be giving a brief on a program they will develop to address these important issues in the military.

**THEY ARE LOOKING FOR VOLUNTEERS TO PARTICIPATE
IN A TWO-HOUR GROUP DISCUSSION THAT WILL TAKE
PLACE DURING WORK-HOURS
(PIZZA AND SODA WILL BE SERVED)**

You have an opportunity to give your opinions and point of view that will help in the development of this health program.

If you are interested, come to a 15-minute brief (*add time and location here*) to learn more about the program and more about the group discussion.

Attachment 2. Focus Group Questionnaires

Preventing Health Damaging Behaviors in Army and Marine Corps Recruits

FOCUS GROUP WITH MILITARY TRAINEES

Circle one: Male Female Co-ed

Welcome, and thank you for agreeing to participate in our group discussion. The purpose of this discussion is to learn about the risk and prevention of sexually transmitted infections, unintended pregnancies, alcohol and other substance misuse, sexual harassment, and sexual violence in soldiers during their first tour of duty.

I am _____ and I am a _____ from the University of California, San Francisco. Also with me today is my colleague _____ also from the University of California, San Francisco. I will let her introduce herself to you. We are collaborating on a research project to determine effective and creative ways of reducing the risk and preventing negative health outcomes in male and female soldiers during their first tour of duty.

The reason you were asked to participate in this discussion today is to provide us with first-hand information about what you see as the most important issues which threaten the health and military readiness of young soldiers. We are particularly interested in your views and opinions. There are no right or wrong answers, but rather differing points of view. Please feel free to share your point of view even if it differs from what others have said. Also, it is important that you do NOT mention any names of other personnel during these focus group discussions. It is also important that you do NOT tell others outside this room what a specific person said. If you believe you cannot adhere to these two requirements, please inform the focus group facilitator immediately. It is also important not to reveal any personal information as there is no guarantee that what you say will not be repeated outside this room by other participants. Revealing confidential information could lead to embarrassment and possible disciplinary actions under the Uniform Code of Military Justice.

Before we begin, I would like to make a few points about how we will run this session:

- (1) The information you provide to us will be utilized to develop health promotion interventions for military trainees.
- (2) The information you provide in this group is confidential; names will not be used in any summary of this discussion.
- (3) Please keep in mind that we are just as interested in the negative comments as the positive comments, and many times the negative comments are the most helpful.
- (4) Our session today will last about two hours and we will not be taking a formal break.

Our first question has to do with your reason for joining the Army.

1. Why did you choose to join the Army?

The next set of questions has to do with sexually transmitted diseases/STDs/VD.

2. What are some common STDs women/men get?
3. How can a person tell if she/he has an STD?
4. What are some symptoms of STDs? Do women/men always have symptoms?
5. Can a woman tell if a man has an STD? Can a man tell if a woman has an STD?
6. What are some complications that men/women may develop after getting an STD?
7. What are some of the biggest challenges men/women have in trying to protect themselves from getting an STD?
8. What are some of the biggest challenges young women have in trying to prevent an unintended pregnancy? What about men?
9. What are some of the reasons why women may not insist that her partner wears a condom?
10. What are some reasons why men may not consistently wear condoms?
11. If you were to come up with a description of the type(s) of person who get STDs, what would that be? (Note for facilitator – these are only prompts if there are no immediate responses– is she/he naïve, one with low self-esteem, ambitious, etc?)
11. What are some of the factors that influence whether men will or will not use condoms to protect himself from STDs?
12. What are some of the factors that influence whether a woman will or will not use birth control methods for preventing unintended pregnancies? What is the role of men?
13. How knowledgeable do you think junior enlisted soldiers are about the different types of birth control that are available?
14. How skillful do you think junior enlisted soldiers are at using birth control? Is it different for men? For women?
15. Do you think that drinking to the point of passing out is a problem for young people your age?
16. Do you think peer pressure plays a role in whether young junior enlisted soldiers drink alcohol to the point of passing out? If yes, what role does it play?

17. Do you think that sexual harassment is a problem for soldiers? We are defining sexual harassment as unwelcome sexual advances, requests for sexual favors, and other verbal or physical conduct. Are there differences for women and men?
18. Is sexual violence is a problem for soldiers? We are defining sexual violence as nonconsensual completed or attempted sexual contact. Are there differences for women and men?

The next few questions have to do with seeking health care.

19. What do you think will happen to someone (or a military career) if they were diagnosed with an STD? Became pregnant as an unmarried woman? Had a problem with alcohol or other substances? Was a victim of sexual harassment or sexual violence?
20. Do you think that if a young military trainee was diagnosed with an STD would he/she talk to his/her immediate supervisor? Had a problem with alcohol or any of substances? Was concerned with or affected by sexual harassment or sexual violence?
21. Have you received information from your command about STDs? Alcohol or other substance use? Sexual harassment? Sexual violence?

The following questions have to do with the type of strategies we should use to develop effective programs that will be of interest to young soldiers like you.

22. What is the most important message we should convey to all young soldiers who will be involved in our programs?
23. What can we say as part of the education program to convince young soldiers that STDs can result in serious health problems that can affect them for years to come?
24. Assuming you have a younger sister/brother, what would you say to her/him about being safe and staying healthy?
25. Given that STDs and pregnancies are personal issues, how can we get young soldiers such as you to be interested in participating in our program? What would be the main reason for not participating in our program?
26. What can we do to convince each participant that we will not share any of the information that is discussed in our program?
27. The routine way to screen women for STDs requires a pelvic examination, however, in our program we will use urine and self-administered vaginal swabs, the size of a q-tip. Do you think these techniques will be acceptable to young women participating in our program? If yes, why? If no, why?

28. What specific information should we give other military trainees who will participate in our program in terms of preventing STDs? Unintended pregnancies? Alcohol or other substance abuse? Sexual harassment? Sexual violence?
29. What skills should we provide to military trainees who will participate in our program regarding prevention of STDs? Unintended pregnancies? Alcohol or other substance abuse? Sexual harassment? Sexual violence?
30. Should the skills be different for women and men? If yes, specifically what should the differences be?
31. Is there any other information that we must be sure to discuss in our program?

Preventing Health Damaging Behaviors in Army and Marine Corps Recruits

FOCUS GROUP WITH JUNIOR ENLISTED SOLDIERS

Circle one: Male Female Co-ed

Welcome, and thank you for agreeing to participate in our group discussion. The purpose of this discussion is to learn about the risk and prevention of sexually transmitted infections, unintended pregnancies, alcohol and other substance misuse, sexual harassment, and sexual violence in soldiers during their first tour of duty.

I am _____ and I am a _____ from the University of California, San Francisco. Also with me today is my colleague _____ also from the University of California, San Francisco. I will let her introduce herself to you. We are collaborating on a research project to determine effective and creative ways of reducing the risk and preventing negative health outcomes in male and female soldiers during their first tour of duty.

The reason you were asked to participate in this discussion today is to provide us with first-hand information about what you see as the most important issues which threaten the health and military readiness of young soldiers. We are particularly interested in your views and opinions. There are no right or wrong answers, but rather differing points of view. Please feel free to share your point of view even if it differs from what others have said. Also, it is important that you do NOT mention any names of other personnel during these focus group discussions. It is also important that you do NOT tell others outside this room what a specific person said. If you believe you cannot adhere to these two requirements, please inform the focus group facilitator immediately. It is also important not to reveal any personal information as there is no guarantee that what you say will not be repeated outside this room by other participants. Revealing confidential information could lead to embarrassment and possible disciplinary actions under the Uniform Code of Military Justice.

Before we begin, I would like to make a few points about how we will run this session:

- (1) The information you provide to us will be utilized to develop health promotion interventions for military trainees.
- (2) The information you provide in this group is confidential; names will not be used in any summary of this discussion.
- (3) Please keep in mind that we are just as interested in the negative comments as the positive comments, and many times the negative comments are the most helpful.
- (4) Our session today will last about two hours and we will not be taking a formal break.

General Perceptions

1. Why do you think young people choose to join the Army?

2. After boot camp, what do think are the most stressful things about being a young soldier? (Career/job? Personal life?)
3. Some people think that many young people in the military get married much younger than their same-age peers who are not in the military. Do you share that perception? Why do you think this is (is not) the case?

Risk Factors

4. Can you tell me your perceptions about social situations for soldiers during military training? Do you think the experiences are the same or different for men and women? In what ways are they the same and in what ways are they different?
5. Can you describe the social situations for soldiers living in barracks during military training?
6. Do you think peer pressure plays a role in whether young junior enlisted soldiers drink alcohol to the point of passing out? If yes, what role does it play?
7. Why do you think soldiers your age have unintended pregnancies while not married or in a long-term relationship?
8. Do you think that STDs such as chlamydia and gonorrhea are a problem for young junior enlisted soldiers?
9. What do you think are the main reasons why young junior enlisted soldiers may not consistently use birth control? Do you think it is different for men and women in the Army?
10. Are there advantages to being active duty, pregnant (or having a child), and being unmarried? Are there any disadvantages?
11. How knowledgeable do you think other young junior enlisted soldiers are about the different types of birth control that are available?
12. How skillful do you think young junior enlisted Army women are at using birth control? What about men?
13. In general, do you think that drinking alcohol to the point of passing out is a problem for young junior enlisted soldiers? Is that a problem in general for men? For women?
14. Can you describe social situations in which young junior enlisted soldiers typically drink? Are there differences in where young women and men in the Army typically drink?
15. Do you think that sexual harassment is a problem for soldiers? We are defining sexual harassment as unwelcome sexual advances, requests for sexual favors, and other verbal or physical conduct. Are there differences for women and men?

16. Is sexual violence is a problem for young soldiers? We are defining sexual violence as nonconsensual completed or attempted sexual contact. Are there differences for women and men?
17. Specifically what do you think is the biggest concern for male soldiers? What is the biggest concern for women soldiers?
18. What do you think is the best solution for addressing sexual harassment in the Army?
19. What do you think is the best solution for addressing sexual violence in the Army?

Health Care Services

20. Where do most young junior enlisted soldiers typically get health care for STDs? For unintended pregnancies?
21. Do you think that female soldiers avoid having pelvic examinations? If yes, why? If no, why not?
22. Do you think that male soldiers avoid being screened for STDs? If yes, why? If no, why not?
23. Are there any barriers or problems to using the military health system for health concerns such as STDs? Unintended pregnancies? Alcohol abuse? Sexual harassment? Sexual violence?
24. Do you think that if a young junior enlisted soldier was diagnosed with an STD would he/she talk to his/her immediate supervisor? Had a problem with alcohol or any of substances? Was concerned with or affected by sexual harassment or sexual violence?
25. Have you received information from your command about STDs? Alcohol and substance abuse? Sexual harassment? Sexual violence?

Interventions

26. What specific information should we give young military trainees who will participate in our program in terms of preventing STDs? Unintended pregnancies? Alcohol and other substance abuse? Sexual harassment? Sexual violence?
27. What skills should we provide to military trainees who will participate in our program regarding prevention of STDs? Unintended pregnancies? Alcohol or other substance abuse? Sexual harassment? Sexual violence?
28. Should the skills be different for men than for women? If yes, specifically what should the differences be?

Attachment 3. Informed Consent Document

Preventing Health Damaging Behaviors in Army and Marine Corps Recruits

**BROOKE ARMY MEDICAL CENTER/WILFORD HALL MEDICAL CENTER
INFORMED CONSENT DOCUMENT**

Preventing Health Damaging Behaviors in Army and Marine Corps Recruits

PRINCIPAL INVESTIGATOR:

Overall: Cherrie B. Boyer, Ph.D. (University of California, San Francisco)

Site: MAJ Caron Wilbur, AN (Ft. Sam Houston, TX)

If you choose not to participate in this research study, your decision will not affect your eligibility for care or any other benefits to which you are entitled.

DESCRIPTION/PURPOSE OF RESEARCH:

You are being asked to consider participation in this research study. Cherrie B. Boyer, PhD and Mary-Ann Shafer from the Department of Pediatrics, Division of Adolescent Medicine at the University of California, San Francisco, and MAJ Caron Wilbur, AN from the 32nd Medical Brigade at Fort Sam Houston are conducting a research study is to prevent and reduce the risk of sexually transmitted infections, unintended pregnancies, alcohol and other substance misuse, and exposure to or involvement with sexual harassment and sexual violence among Army and Marine Corps personnel during their first tour of duty. To accomplish this goal, we will implement an intervention for recruits and other junior enlisted personnel in both branches of the military. In order to develop the interventions, we will have small group discussions (focus groups) to gather information regarding junior enlisted Army personnel's knowledge, attitudes, beliefs, and behaviors associated with the risk and prevention of sexually transmitted infections, unintended pregnancies, alcohol and other substance misuse, sexual harassment, and sexual violence. This study is being funded by the Department of Defense, Army Medical and Material Command at Fort Detrick Maryland. You are being asked to participate in this study because you are currently working at Fort Sam Houston. Participation in this study is completely voluntary. You do not have to participate and choosing to do so will not have a negative impact on your military training or career.

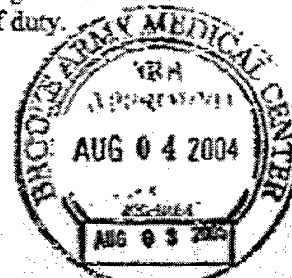
This study will enroll approximately 168 subjects overall, with approximately 84 subjects to be enrolled at the 32nd Medical Brigade, over a period of about 90 days.

During your participation in this study, you will be asked to participate in one, two-hour focus group session.

You have been selected to voluntarily participate in this study because you are a junior enlisted soldier and are currently based at Fort Sam Houston. We are interested in junior enlisted soldiers' knowledge, attitudes, beliefs, and behaviors associated with the risk and prevention of sexually transmitted infections, unintended pregnancies, alcohol and other substance misuse, sexual harassment, and sexual violence in order to develop a prevention intervention program to address these health factors for junior enlisted military personnel during their first tour of duty.

Rev. 25 September 2004

Page 1 of 5



Preventing Health Damaging Behaviors in Army and Marine Corps Recruits

PROCEDURES:

If you volunteer to participate in this study:

1. You will participate in a single two-hour focus group discussion with other individuals in your rank. Overall, there will be two separate co-ed focus groups, two separate focus groups with males, and two with females. Each focus group will consist of 5-7 participants.
2. During the focus group discussion names or other personal identifying information shall not be used. You and other members of the group will be asked to discuss your knowledge, attitudes, and beliefs about the risk and prevention of sexually transmitted infections, unintended pregnancies, alcohol and other substances, sexual harassment, and sexual violence among young men and women in your age group. We will not ask you to disclose your personal behaviors related to these health issues. We are only interested in you providing your general perceptions about these health behaviors among your peers, especially those in your rank.
3. An audiotape will be made of this discussion. This discussion is expected to last no longer than two hours.
4. The focus groups will be lead by Drs. Boyer and Shafer. Instructors or any other military personnel will not be present during these discussions.
5. Your names or any other personal identification will not be used during the focus group discussion or any of the summaries of the discussions. This information will be used to develop an effective intervention program for soldiers during their first tour of duty.
6. The focus groups will take place in a classroom on base.

RISKS OR DISCOMFORTS:

1. Some of the focus group discussion questions may make you uncomfortable or may be embarrassing. You do not have to answer any questions that you feel uncomfortable answering and you can leave the group at any time.
2. It is important for you to not repeat any information discussed within the group after you leave. Additionally, do not disclose specific information about your own personal experiences with alcohol, drugs, sex or criminal activities. Revealing information of this nature could lead to disciplinary action under the UCMJ.
3. Participation in research may involve a loss of privacy; however, the audio tapes and transcripts of the focus groups will be handled as confidentially as possible. Every attempt to avoid use of personal identifying information (such as names) during the discussion will be made. Transcripts of the audio tapes will contain only your gender and will not contain any names. The researchers will ask you and other participants to not use names during the group session. They will also ask group members not to tell anyone outside the group what any

Rev. 25 September 2004

Page 2 of 5



Preventing Health Damaging Behaviors in Army and Marine Corps Recruits

particular person said in the group. However, the researchers cannot guarantee that everyone will keep the discussions private. Only researchers involved in this project will have access to the audiotapes or transcripts of the tapes. After the group discussion has been transcribed from the tapes, the tapes will be destroyed. No individual identities will be used in any reports or publications that may result from this study.

4. If, during the course of the focus group discussion you show signs of or report psychological discomfort or distress during or immediately following the discussion, Drs. Boyer or Shafer will inform your instructor with a request for referral for immediate care to a base Psychologist or Chaplain.

BENEFITS:

There will be no direct benefit to you from participating in this study. However, the information that you provide may help us develop an effective intervention to prevent health problems such as sexually transmitted infections, unplanned pregnancies, alcohol and other substance misuse, sexual harassment, and sexual violence among young soldiers during their first tour of duty.

PAYMENT (COMPENSATION):

You will not receive any compensation (payment) for participating in this study.

ALTERNATIVES TO PARTICIPATION:

Choosing not to participate in this study is your alternative to volunteering for the study. Choosing not to participate in this study will have no impact on your current military training or military career.

CONFIDENTIALITY OF RECORDS OF STUDY PARTICIPATION:

Records of your participation in this study may only be disclosed in accordance with federal law, including the Federal Privacy Act, 5 U.S.C. 552a, and its implementing regulations.

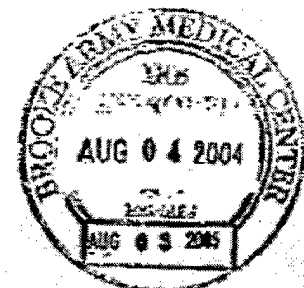
By signing this consent document, you give your permission for information gained from your participation in this study to be published in medical literature, discussed for educational purposes, and used generally to further medical science. You will not be personally identified; all information will be presented as anonymous data.

Your records may be reviewed by the U.S. Food & Drug Administration (FDA), other government agencies, the BAMC/WHMC Institutional Review Board, and the University of California, San Francisco Committee on Human Research, the U.S. Army Medical Research and Materiel Command and by the Human Subject Research Review Board (HSRRB).

Complete confidentiality cannot be promised, particularly for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities.

Rev. 25 September 2004

Page 3 of 5



Preventing Health Damaging Behaviors in Army and Marine Corps Recruits

ENTITLEMENT TO CARE:

In the event of injury resulting from this study, the extent of medical care provided is limited and will be within the scope authorized for Department of Defense (DoD) health care beneficiaries

Your entitlement to medical and dental care and/or compensation in the event of injury is governed by federal laws and regulations, and if you have questions about your rights as a research subject or if you believe you have received a research-related injury, you may contact the Brooke Army Medical Center Protocol Coordinators, (210) 916-2598 or BAMC Judge Advocate General, (210) 916-2031.

VOLUNTARY PARTICIPATION:

The decision to participate in this study is completely voluntary on your part. No one has coerced or intimidated you into participating in this project. You are participating because you want to. The Principal Investigator or one of her associates has adequately answered any and all questions you have about this study, your participation, and the procedures involved.

You may withdraw this consent at any time and discontinue further participation in this study without affecting your eligibility for care or any other benefits to which you are entitled. Should you choose to withdraw, you must inform the person(s) who will be conducting the focus groups.

The Principal Investigator or the focus group facilitator may terminate your participation in this study at any time if they feel this to be in your best interest.

CONTACT INFORMATION:

Principal Investigator (PI)

The Principal Investigators will be available to answer any questions concerning your participation in the focus groups.

Overall PI: Dr. Cherric B. Boyer

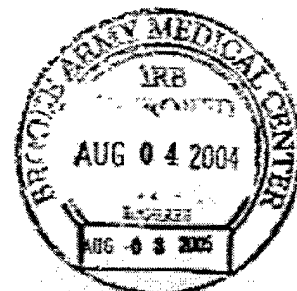
Phone: (415) 514-3672

Local PI: MAJ Caron Wilbur, AN

Phone: (210) 221-3118

Rev. 25 September 2004

Page 4 of 5



Preventing Health Damaging Behaviors in Army and Marine Corps Recruits

Your consent to participate in this study is given on a voluntary basis. All oral and written information and discussions about this study have been in English, a language in which you are fluent. A copy of this form has been given to you.

Volunteer's Signature Volunteer's SSN Phone # Date

Volunteer's Printed Name FMP Sponsor's SSN Date of Birth

Volunteer's Address (street, city, state & zip code)

Advising Investigator's Signature Date Phone Number

Advising Investigator's Printed Name

Witness' Signature Date
(Must witness ALL signatures)

Witness' Printed Name

Rev. 25 September 2004

Page 5 of 5



APPENDIX C. REVIEW FOR PROTECTION OF HUMAN RESEARCH VOLUNTEERS FROM RESEARCH RISKS

INSTITUTIONAL REVIEW BOARD RECOMMENDATION

INITIAL REVIEW

Date of Review: 20 May 2004

Protocol Number: NHRC.2004.0023

Title of Research Protocol: Preventing Health Damaging Behaviors in Army and Marine Corps Recruits

Principal Investigator: Cherrie B. Boyer, PhD (University of California, San Francisco)

Approximate Dates of the Research: August 2004 to 30 September 2005

Outside investigator, Cherrie B. Boyer, PhD (University of California, San Francisco) submitted this protocol to the NHRC IRB for review to comply with the requirement that all research involving Navy or Marine Corps personnel be reviewed by a Naval IRB. This study had previously been reviewed and approved by the UCSF Committee on Human Research and will also subsequently receive Army review. The Naval Health Research Center only reviewed the portions of this project that are directly applicable to Marine Corps personnel.

This study seeks to interview recruits and junior enlisted personnel about potentially health-damaging behaviors so that preventative disease education and health promotion strategies can be developed. Toward that end, volunteers will be recruited to participate in focus groups. Participants will not be identified with particular comments they make during the interviews, and audio tapes will be destroyed shortly after transcriptions of the tapes are made. It is noted that there is also a requirement for multi-service personnel surveys and focus groups to be approved by the Defense Manpower Data Center in Arlington, VA.

With a vote of 6 for, 0 against, Chair abstaining, and no members disqualified from the review, the Board classified this protocol as minimal risk. On a vote of 6 for, 0 against, Chair abstaining, and no members disqualified from the review, the Board voted to recommend approval of this protocol contingent upon minor modifications. Those modifications have been made and approval is recommended for the portions of this study applicable to Marine Corps personnel.

The next scheduled review is on or before 19 May 2005.

Christopher G. Blood, JD, MA
Chair, NHRC IRB


Signature & Date

Acknowledged by:


James T. Luz, Commanding Officer, NHRC

22 JUL 04
Date

HUMAN USE PROTOCOL ROUTING SLIP

FROM (Principal Investigator):
Cherrie B. Boyer, PhD
(TYPED NAME)

Cherrie B. Boyer, PhD
(SIGNATURE)

In accordance with NAVHLTHRSCHCENINST 3900.2B, I am submitting the attached human use protocol for consideration.

TITLE OF PROTOCOL: Preventing Health Damaging Behaviors in Army and Marine Corps Recruits

ABBREVIATED TITLE: Preventing Health Damaging Behaviors

PROPOSED DATES OF RESEARCH: August 30, 2004 to November 30, 2004. However it is important to note that these dates are highly dependent upon when we are able to obtain approval of IRBs at Brooke Army Medical Center the Naval Health Research Center, and the Human Subjects Research Review Board (HSRRB) at Fort Detrick. We have current IRB approval from the University of California, San Francisco, but will need to also obtain approval for the newly requested modifications to the consent forms and focus group questions.

SUBMISSION (CHECK ONE):

- ☒ INITIAL SUBMISSION
☐ MODIFICATION OF PREVIOUS SUBMISSION
☐ CONTINUING/ANNUAL REVIEW

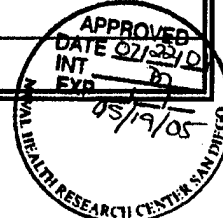
PROTOCOL OBJECTIVE (Brief sentence or two): The overall purpose of the proposed research is to: (1) prevent sexually transmitted infections (STIs), unintended pregnancies (UIPs), alcohol and other substance misuse, and exposure to or involvement with sexual violence in Marine Corps recruits and Army advance individual trainees (AIT).

COMMENTS (e.g., issues, special considerations): This is a multi-phased study. Although the overall goals are to develop, implement, and evaluate a cognitive-behavioral skills-building intervention to prevent sexually transmitted infections, unintended pregnancies, alcohol misuse, and involvement with and exposure to sexual violence among Army AIT trainees and Marine Corps recruits, we are seeking approval only for the elicitation (focus group) phase of the study at this time. Information collected from the focus groups will be used for the development of the interventions as well as for the development of the pre- and post-intervention evaluation questionnaires.

DoD PROTOCOL NUMBER (Assigned by IRB Administrator upon submission for initial review. Be sure to add this number where indicated on the title page): NHRC.2004.0023

Note: You must obtain signatures 1-4 before you submit the protocol to the IRB.

		DATE RECEIVED	DATE APPROVED	INITIALS
1	PROGRAM MANAGER			
2	PROGRAM IRB MEMBER			
3	DIRECTOR OF SCIENCE AND TECHNOLOGY			
4	IRB ADMINISTRATOR			
5	COMMANDING OFFICER			



I. COVER PAGE(S)

1. Protocol Number: NHRC.2004.0023
2. Title: Preventing Health Damaging Behaviors in Army and Marine Corps Recruits
3. Date of Submission: 15 July 2004
4. Approved Work Unit Title (i.e., the funded research proposal [or also referred to as the work unit] title under which the protocol is being conducted) and Full Work Unit Number:

We have no current work unit. However, this research is funded by the United States Army Medical Research and Materiel Command, Fort Detrick Maryland. The official award number is: Wx81WH-04-1-0159.

5. Approximate Dates of Research (e.g., yymmdd, 961212 to 980930): 040830 to 041130
6. Principal Investigator: Cherrie B. Boyer, PhD
University of California, San Francisco
7. Co-Investigator(s): Mary-Ann Shafer, MD
University of California San Francisco

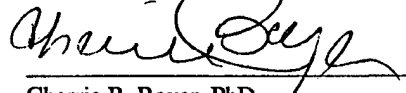
Julius Schachter, PhD
University of California, San Francisco

CPT Lolita Burrell, PhD
Medical Services Corps, USARIEM/WAMC Medical Research Facility

LTC Caron Wilbur, Army Nurse Corps, Brooke Army Medical Center
8. Primary Performing Institution(s): University of California, San Francisco is the primary performance site. Fort Sam Houston, San Antonio, TX, 32nd Medical Brigade and the Marine Corps Recruiting Depot, Parris Island, SC are the sites where the focus group data will be collected.
9. Collaborating Institution(s): N/A
10. Subjects:
 - a. Number of Subjects: approximately 168
 - b. Number of Female Subjects: approximately 84
 - c. Number of Male Subjects: approximately 84
 - d. Number of Civilian Subjects: 0
 - e. Number of Active-Duty Subjects: 168
11. Identification of Medical Monitor: N/A
12. Has a JRA/CRDA/MOU been initiated? (Y/N): No

II. SIGNATURE PAGE(S) (Please see following pages for other signatures)

1. Principal Investigator:


Cherrie B. Boyer, PhD
University of California, San Francisco

2. Co-Investigator:

Mary-Ann Shafer, MD
University of California, San Francisco

Julius Schachter, PhD
University of California, San Francisco

CPT Lolita Burrell, PhD
Medical Services Corps, USARIEM/WAMC Medical Research Facility

LTC Caron Wilbur, Army Nurse Corps, Brooke Army Medical Center

3. Medical Monitor:

N/A

4. Key Support Personnel:

Allison Friedman, Research Assistant, University of California, San
Francisco, Division of Adolescent Medicine

Richard A. Shaffer, PhD, Project Consultant, Naval Health Research
Center

5. Program Manager:

N/A

6. Director of Science:
and Technology

Paula Konoske, Ph.D.

7. Commanding Officer:

James T. Luz
CAPT MSC USN

II. SIGNATURE PAGE(S)

1. Principal Investigator:

[PI Last Name], [PI First Name], [PI Middle Name]
[PI Title]
[PI Institution]

2. Co-Investigator:

Mary Ann Shafer
Mary-Ann Shafer, MD
[Co-Investigator Title]
[Co-Investigator Institution]

[Co-Investigator Last Name], [Co-Investigator First Name], [Co-Investigator Middle Name]
[Co-Investigator Title]
[Co-Investigator Institution]

[PI Last Name], [PI First Name], [PI Middle Name]
United States Army Research Institute
of Environmental Medicine

[Co-Investigator Last Name], [Co-Investigator First Name], [Co-Investigator Middle Name]
[Co-Investigator Title]
[Co-Investigator Institution]

[Co-Investigator Last Name], [Co-Investigator First Name], [Co-Investigator Middle Name]
[Co-Investigator Title]
[Co-Investigator Institution]

3. Medical Monitor:

[Medical Monitor Last Name], [Medical Monitor First Name], [Medical Monitor Middle Name]
[Medical Monitor Title]
[Medical Monitor Institution]

4. Key Support Personnel:

[Name]
[Title]

[Name]
[Title]

5. Program Manager:

[Name]
[Head Division Name]

6. Director of Science:
and Technology

Paula Konoske, Ph.D.

7. Commanding Officer:

James T. Luz
CAPT MSC USN


II. SIGNATURE PAGE(S)

1. Principal Investigator:

Cherrie B. Boyer, PhD
University of California, San Francisco

2. Co-Investigator:

Mary-Ann Shafer, MD
University of California, San Francisco


Julius Schachter, PhD
University of California, San Francisco

CPT Lolita Burrell, PhD
United States Army Research Institute
of Environmental Medicine

[Co-I4 Full Name]
[Co-I4 Affiliation]

[Co-I5 Full Name]
[Co-I5 Affiliation]

3. Medical Monitor:

[Monitor Full Name]
[Medical Monitor Affiliation]

4. Key Support Personnel:

[Name]
[Title]

[Name]
[Title]

5. Program Manager:

[Name]
[Head, Division Name]

6. Director of Science:
and Technology

Paula Konoske, Ph.D.

7. Commanding Officer:

James T. Luz
CAPT MSC USN

II. SIGNATURE PAGE(S)

1. Principal Investigator:

Cherrie B. Boyer, PhD
University of California, San Francisco

2. Co-Investigator:

Mary-Ann Shafer, MD
University of California, San Francisco

Julius Schachter, PhD
University of California, San Francisco

Lolita Burrell
CPT Lolita Burrell, PhD
Medical Services Corps, USARIEM/WAMC Medical Research
Facility

3. Medical Monitor:

N/A

4. Key Support Personnel:

Kelli Betsinger, Research Assistant, University of California, San
Francisco, Division of Adolescent Medicine

Susan Pierce, Project Assistant, University of California, San
Francisco, Division of Adolescent Medicine

5. Program Manager:

Richard Shafer, PhD
Clinical Epidemiology

6. Director of Science:
and Technology

Paula Konoske, Ph.D.

7. Commanding Officer:

James T. Luz
CAPT MSC USN

II. SIGNATURE PAGE(S) (Please see following pages for other signatures)**1. Principal Investigator:**


Cherrie B. Boyer, PhD
University of California, San Francisco

2. Co-Investigator:

Mary-Ann Shafer, MD
University of California, San Francisco

Julius Schachter, PhD
University of California, San Francisco

CPT Lolita Burrell, PhD
Medical Services Corps, USARIEM/WAMC Medical Research Facility


LTC Caron Wilbur, M.S.
Army Nurse Corps, Brooke Army Medical Center

3. Medical Monitor:

N/A

4. Key Support Personnel:

Allison Friedman, Research Assistant, University of California, San Francisco, Division of Adolescent Medicine

Richard A. Shaffer, PhD, Project Consultant, Naval Health Research Center

5. Program Manager:

N/A

**6. Director of Science:
and Technology**

Paula Konoske, Ph.D.

7. Commanding Officer:

James T. Luz
CAPT MSC USN

II. SIGNATURE PAGE(S)

1. Principal Investigator:

Cherrie B. Boyer, PhD
University of California, San Francisco

2. Co-Investigator:

Mary-Ann Shafer, MD
University of California, San Francisco

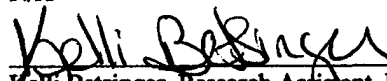
Julius Schachter, PhD
University of California, San Francisco

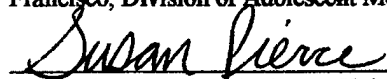
CPT Lolita Burrell, PhD
Medical Services Corps, USARIEM/WAMC Medical Research
Facility

3. Medical Monitor:

N/A

4. Key Support Personnel:


Kelli Betsinger, Research Assistant, University of California, San
Francisco, Division of Adolescent Medicine


Susan Pierce, Project Assistant, University of California, San
Francisco, Division of Adolescent Medicine

5. Program Manager:

Richard Shafer, PhD
Clinical Epidemiology

6. Director of Science:
and Technology

Paula Konoske, Ph.D.

7. Commanding Officer:

James T. Luz
CAPT MSC USN

II. SIGNATURE PAGE(S) (Please see following pages for other signatures)

1. Principal Investigator:

Cherrie B. Boyer, PhD
University of California, San Francisco

2. Co-Investigator:

Mary-Ann Shafer, MD
University of California, San Francisco

Julius Schachter, PhD
University of California, San Francisco

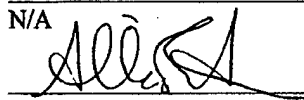
CPT Lolita Burrell, PhD
Medical Services Corps, USARIEM/WAMC Medical Research Facility

LTC Caron Wilbur, Army Nurse Corps, Brooke Army Medical Center

3. Medical Monitor:

N/A

4. Key Support Personnel:



Allison Friedman, Research Assistant, University of California, San Francisco, Division of Adolescent Medicine

Richard A. Shaffer, PhD, Project Consultant, Naval Health Research Center

5. Program Manager:

N/A

6. Director of Science:
and Technology

Paula Konoske, Ph.D.

7. Commanding Officer:

James T. Luz
CAPT MSC USN

III. RECORD OF CHANGES TO THE PROTOCOL: N/A

IV. TABLE OF CONTENTS

I. COVER PAGE(S).....	ii
II. SIGNATURE PAGE(S)	iii
III. RECORD OF CHANGES TO THE PROTOCOL: N/A	iv
IV. TABLE OF CONTENTS	i
V. SCIENTIFIC BACKGROUND AND OBJECTIVES	1
1. Background	1
2. Objectives.....	3
A. Hypothesis(es) to be tested	3
B. Other objective(s)	3
VI. EXPERIMENTAL METHODS	4
1. Experimental Procedures and Rationale	4
A. Subjects	4
B. Methods and Informed Consent Plan	4
2. Sample Size Determination With Statistical Power Calculation.....	5
3. Justification for Exclusion of Specific Groups	5
4. Required Equipment and Supplies.....	5
VII. ORGANIZATION OF RESEARCH EFFORT	5
1. Duties and Responsibilities.....	5
VIII. RISKS AND DISCOMFORTS TO RESEARCH VOLUNTEERS	6
1. Risk to the Volunteer and Means of Mitigation	6
2. Special Risks to Pregnant Women.....	6
3. Safety Precautions and Emergency Procedures.....	6
4. Assessment of Sufficiency of Plans to Deal With Untoward Events or Injuries	6
5. Qualification of Medical Monitor and Medical Support Personnel.....	6
IX. DESCRIPTION OF THE SYSTEM FOR MAINTENANCE OF RECORD	7
1. Experimental Data.....	7
2. Research Protocol, Consent Forms, and Related Documents for Protection of Human Research Volunteers	7
3. Individual Medical Records.....	7
X. APPENDICES	7
A. INVESTIGATOR ASSURANCE AGREEMENTS(s).....	A-1
B. REVIEW FOR PROTECTION OF HUMAN RESEARCH VOLUNTEERS	B-1
C. POSTAPPROVAL DOCUMENTATION: N/A	C-1
D. SPECIAL REPORTS: N/A.....	D-1
E. REFERENCES.....	E-1
F. NONTECHNICAL SYNOPSIS	F-1
XI. ATTACHEMENTS (See Page 7)	

V. SCIENTIFIC BACKGROUND AND OBJECTIVES

1. Background

Significance:

Building on our previous military research, we plan to evaluate a state-of-the-science cognitive-behavioral, skills-building intervention to prevent and reduce recruits' risk for sexually transmitted infections (STIs), unintended pregnancies (UIPs), alcohol and other substance misuse, and exposure to or involvement with sexual violence. Given current trends for integrated military training of males and females, this research also seeks to establish the best training practices for educating young troops about sensitive and critical health issues that impact military performance and readiness. Currently, there is little empirical evidence which address the issue of best health education practice, especially among young adults. This research will have direct application for health promotion and disease prevention education strategies designed to reach military men and women early in their careers.

Military Relevance:

Providing health promotion and disease prevention education strategies to military men and women early in their careers will benefit the military by reducing the healthcare costs associated with sexually transmitted infections and their sequelae of ectopic pregnancy, tubal infertility, pelvic inflammatory disease, and increased risk of exposure to the human immunodeficiency virus (HIV). In addition, health promotion and disease prevention education has the potential of reducing the financial burdens associated with substance abuse, sexual violence and unintended pregnancies. Additional cost savings may occur in the form of reduced attrition rates that may be associated with these health issues. This research will also benefit the military not only by promoting health readiness but also by promoting mission readiness. Mission readiness may be compromised through factors such as lost duty days and decreased physical fitness that may occur as outcomes of decreased health readiness.

Background/ Review of Literature:

The health damaging behaviors of young military recruits are reflections of the health problems facing all young people in the United States. Military life presents additional opportunities and challenges that may both protect and place its young troops at risk for engaging in health damaging behaviors. Preventable challenges for maintaining a healthy armed force include the high rates of STIs, UIPs, misuse of alcohol and other substances as well as the presence of sexual violence within our young troops. The common thread through these negative health outcomes is volitional behavior. Such behaviors not only result in illness or injury, but may also negatively impact performance of military duties and thereby threaten military readiness. Nationally, the military has taken leadership in setting standards and policies regarding professional behavior and universal health care not only for reproductive health, but also for preventing misuse of alcohol and other substances and for eliminating sexual violence. However, among our young troops, STIs remain epidemic, more than two-thirds of pregnancies are unintended, alcohol misuse is prevalent, and sexual violence remains a problem. Therefore, a gap exists between expected and actual health behaviors and outcomes that may negatively affect military performance and readiness. Promising results from our prevention interventions targeting Marine Corps males prior to deployment¹ and Marine Corps female recruits² show reductions in adverse health behaviors and outcomes, including alcohol misuse, risky sexual behaviors, UIPs, and STIs.

Sexually Transmitted Infections

STIs, the most common infections of young adults, are associated with major preventable health morbidity especially in women (e.g., PID, ectopic pregnancy, infertility) and their offspring (e.g., congenital infection complications). As with the population at-large, STIs are also very common among young military recruits and active duty personnel. Screening rates using nucleic acid amplification tests (NAATs) applied to urine of Army female recruits yielded a chlamydia rate of 9%.³ Our group's study of STI screening of Marine Corps female recruits yield an overall STI rate of 14% (11% for chlamydia, 2% for gonorrhea, 1% for trichomonas) using urine, endocervical, and self-administered vaginal swab specimens.^{4,5} These rates of chlamydia for Army and Marine Corps female recruits are twice that reported for similar-aged women attending family planning clinics⁶. STIs in active duty personnel reveal similarly high rates. For example, in a group of active duty Navy women, chlamydia prevalence was 7% using NAATS applied to urine. Among Army male recruits, chlamydia was 5% and gonorrhea was detected in 0.6% using NAATs

applied to urine.⁷ Among active duty Marine Corps men on deployment in Okinawa, Japan who were screened by NAATs urine tests, chlamydia was detected in 5% of the sample.⁸ Among male Marines screened just prior to a deployment to the western Pacific, 4% had chlamydia with no gonorrhea detected.⁹ Our group has further defined the prevalence of the syndrome bacterial vaginosis (BV) among Marine Corps female recruits (27%), which has been related to premature births in infected women.¹⁰ Control of STIs, especially through chlamydial screening of asymptomatic women, has been shown by our group and others (military) to be cost-effective.^{11, 12}

Unintended Pregnancies

UIPs in young military women place the woman, her family, and the military potentially at risk for not accomplishing their respective missions. There is evidence to show that pregnancy outcomes for military women fare worse than comparable civilian women showing more premature births, and other complications.^{13, 14} Furthermore, there is the constant concern of any pregnancy, but especially ectopic pregnancy, occurring while military women are on deployment. Like civilian women, most pregnancies are unintended (55%).¹⁵ Data from our recent study of Marine Corps female recruits who were followed during their first year of military service showed an overall pregnancy rate of 18% of which two-thirds were unintended (unpublished data). Prevention of both STI acquisition and unintended pregnancy in young military men and women is necessary to assure the health of young military population and to ensure the readiness mission of our armed forces.

Alcohol and Other Substance Use and Misuse

The high prevalence of alcohol and other substance use in young adults poses a significant threat to their health and well-being. National data indicate that 44% of U.S. adults (ages 18 and over) report current drinking, that is, consuming at least 12 drinks of alcohol in the preceding year. The rate of current alcohol use among adults is highest (64%) in the 18-25 age group.¹⁶ Similarly, 14% of persons aged 18-25 reported heavy alcohol use (five or more drinks on one occasion at least once a week in the prior month), with 18% occurring in persons aged 21 years.¹⁶ As in the civilian population, rates of alcohol in military personnel are high, although there have been documented decreases in illicit drug use over the last two decades.¹⁷ Among the 16,000 military personnel responding to the 1995 Department of Defense (DOD) survey of health-related behaviors, rates of heavy alcohol use was documented among 5% of women and 19% of men. Similarly, illicit drug use was 5% for women and 7% for men.¹⁷ Less is known about military recruits. However, one study of 2,002 Naval recruits indicate that 75% of recruits consumed alcohol in the year before enlistment, and 26% engaged in heavy drinking, and 31% reported other substance use. Our recent research among Marine Corps female recruits indicates that in the month prior to enlistment, 67% reported alcohol use and 6% reported substance use, and 57% engaged in sexual intercourse under the influence of alcohol and/or drugs.⁴ Taken together these data suggest the need for interventions to reduce the misuse of alcohol and other substances among military recruits that might later interfere with performance of their military duties and ultimately military readiness.

Sexual Violence

Research has consistently revealed high rates of sexual violence among military personnel.¹⁸⁻²¹ For example, one study of Army soldiers found that one-fifth (23%) of the women reported a history of rape, and 51% of women and 7% of men reported any sexual assault,¹⁸ of which a majority occurred before the soldiers entered the military, primarily during childhood. The 1995 DOD-wide survey showed that 55% of women and 14% of men experienced at least one incident of unwanted sexual attention during the preceding year. Although these rates represent a decline from previous years, the decline in the Army was noted to be less.¹⁹ Among Army women, this research found that 61% had experienced sexual harassment while 18% experienced sexual coercion, and 5% experienced sexual assault.¹⁹ Additionally, a national cross-sectional survey of 558 women veterans who served in the military during Vietnam and subsequent eras was conducted to assess military environmental factors associated with rape during military service. This research indicates that rape was reported in 28% of the women, with consistent rates found across all the time periods.²⁰ Military environmental factors that were associated with increased likelihood of rape included sexual harassment allowed by officers ($p<0.0001$), unwanted sexual advances while on-duty ($p<0.00001$), and while in sleeping quarters ($p<0.0001$). Overall, these data indicate that there is a gap between the military's "zero tolerance" towards sexual violence and the ongoing problems of sexual violence in the armed services. Therefore, sexual violence remains an important health risk to both military women and men and their families, suggesting that early interventions are necessary to decrease negative health outcomes associated with sexual violence and to provide an environment where both men and women feel respected and safe, thereby protecting the

cohesion that is necessary to fulfill the overall mission of the DOD.

Interventions to Prevent Health Damaging Behaviors

Research has shown that STI and HIV prevention interventions that are based on cognitive-behavioral principles are effective strategies for building skills and/or modifying behaviors associated with the acquisition of STI and HIV infections in various populations.²²⁻²⁶ However, none of the studies involved military personnel. However, our recent interventions based on cognitive-behavioral skills-building principles implemented in young Marine Corps males prior to deployment¹ and Marine Corps female recruits² have shown promise for reducing health damaging behaviors and negative health outcomes and their sequelae in this young population. Building on our groups' research and the basic research by others, which identify correlates of STIs,^{4, 27} unplanned pregnancies⁸, alcohol use,^{9, 17, 28} and sexual violence^{19, 20} in military personnel, we plan to develop and evaluate interventions that will target these key factors. Importantly, the proposed interventions will capitalize on military-specific factors that are both health promoting and health damaging. We will target recruits for a number of important reasons: (1) the high rates of STIs among military recruits; (2) many recruits enter military service with a history of alcohol and other substance use; and (3) many women and some men come to the military with a history of exposure to sexual violence. Furthermore, since previous research suggests that gender-specific interventions are key to successful STI and HIV prevention,^{29, 30} we will also examine whether an intervention that gender-integrated versus interventions that are gender-separate are more effective in preventing STIs, UIPs, misuse of alcohol and other substances, and sexual violence. The manner in which the Army (co-ed) and the Marine Corps (gender separate) train their recruits and young enlisted personnel provides a unique opportunity to assess this important health education question.

The proposed intervention will build on our previous work and will be guided by the Information, Motivation, and Behavioral Skills (IMB) model.³¹ The IMB posits that information, motivation, and behavioral skills are the primary determinants of AIDS-preventive behavior. Specifically, the model asserts that information regarding the transmission and prevention of AIDS is a necessary prerequisite of risk-reduction behavior. Motivation to change risk behaviors is a determinant of prevention and affects whether one acts on one's knowledge regarding the transmission and prevention of AIDS. The IMB also asserts that motivation to engage in preventive behaviors is a function of one's attitudes toward the behavior and of perceived norms regarding preventive behaviors. Other critical factors hypothesized to influence motivation to engage in AIDS-preventive behaviors are perceived vulnerability to AIDS and intention to engage in preventive behaviors regarding AIDS. Behavioral skills for engaging in specific preventive behaviors are a third determinant of AIDS-preventive behaviors and affect whether even a knowledgeable, highly motivated person will be able to change his or her behavior to prevent negative health outcomes. Requisite skills to engage in preventive behaviors include the ability to effectively communicate with one's sexual partner about safer sex, to refuse to engage in unsafe sexual practices, and to properly use condoms. In addition to possessing these skills, individuals who practice preventive skills are presumed to have a strong self-belief (self-efficacy) in their ability to practice these preventive behavioral skills. We will extend this model to assess STIs, UIPs, alcohol and substance use, and sexual violence.

2. Objectives

A. Hypothesis(es) to be tested

We are seeking IRB approval only for the elicitation phase (focus group) of the study. This phase is not designed for hypothesis testing. Rather the focus groups will allow for examination of specific themes and/or categories of information that will be used in the development of the interventions.

B. Other objective(s)

There are no other objectives for this phase of the study.

VI. EXPERIMENTAL METHODS

1. Experimental Procedures and Rationale

A. Subjects

Potential participants will include male and female Marine Corps recruits, Army AIT trainees, and other (junior enlisted) active duty military personnel who can provide information about the risks and/or prevention of STIs, UIPs, alcohol and other substance misuse, and sexual violence within the military context. Participation will be voluntary. All potential participants will be fluent in English and able to provide written, informed consent. Our previous research and that of others show that adolescents are at increased risk for many of the health damaging behaviors and negative health outcomes that are the focus of this research.¹⁻²³ Therefore, it is important to include adolescents in this research.

B. Methods and Informed Consent Plan

Recruits/AIT trainees: We will seek volunteers to participate in focus group discussions. For recruits and AIT trainees, we will ask for volunteers only within each training platoon or AIT class during a time in which they are already convened for training purposes. A script of points to be emphasized will be provided to drill instructors for recruits and class instructors for AIT trainees to introduce a member of our research team who will provide an overview of the study and to request volunteers to participate in the elicitation phase of the study (see Attachment 1 for the instructors' introductory script). Therefore, all recruits/trainees within the Command-identified platoons/class that are eligible for participation will have an opportunity to learn about the study. As with our previous research, drill instructors or any other military personnel will not be present during study recruitment in order to avoid feelings of coercion or undue pressure. Recruitment and focus group participation will take place during regularly scheduled periods of training (see Attachment 2 for the recruitment script).

Non-training junior enlisted personnel: Junior enlisted personnel who are not in training will be invited to attend a brief to learn about the study through a flyer that will be provided to all Command-identified Unit Commanders (see Attachment 3 for a copy of the recruitment flyer). As with our previous research, no military personnel other than potential participants will be present during study recruitment in order to avoid feelings of coercion or undue pressure. Recruitment and focus group participation will take place during work hours at or near their places of work.

Consenting Process: Drs. Boyer and Shafer will provide a Brief (overview) of the overall goals and purpose of the study as well as the goals and purpose of the elicitation phase of the study. For recruits and AIT trainees, the Brief will be provided within each of the training platoons/class without drill instructors or other active duty personnel present. After the Brief, recruits and AIT trainees will be invited to participate in a two-hour focus group discussion that will take place at a later predetermined time. Based on our previous experience, we anticipate that most of the recruits and AIT trainees will want to participate, therefore, we will randomly select up to 7 individuals from each of the platoons/class who indicate their willingness to volunteer to participate in the focus groups (each recruit/AIT trainee will be given a number when they enter the Brief; 7 numbers will be chosen based on a random assignment table). These individuals will be asked to remain in the room after the Brief is over. At this point, these individuals will be given a copy of the Experimental Subjects Bill of Rights Statement and will be given an opportunity to read the informed consent statement, ask questions, and sign the consent statement (see Attachment 4 for a copy of this statement which is required by the University of California, San Francisco's Committee on Human Research to be given to all subjects participating in research).

For active duty (non-training) military personnel, flyers inviting them to come hear a Brief about the study will be posted in and around the Command-identified units. Briefs will be provided only to those individuals who choose to attend the Briefs. After the Briefs are completed, up to 7 individuals from each unit will be invited to participate in the focus groups as described above (see Attachment 5 for a copy of the consent forms which have been approved by

the University of California, San Francisco's Committee on Human Research; also see Attachment 6 for the this committee's letter of approval for conducting the elicitation phase of this study).

2. Sample Size Determination With Statistical Power Calculation

Since the elicitation phase of the study is not powered to test specific hypotheses, sample size calculations were not used to determine the number of participants. Overall there will be 24 focus groups, half will occur among Army participants and half will be among Marine Corps participants as described above. Each focus group discussion will consist of 5-7 participants each, which has been identified as an ideal number for such group discussion.²⁴ The number of groups was chosen in order to obtain a representative sample of the target group.

3. Justification for Exclusion of Specific Groups

Potential participants will include male and female Marine Corps recruits, Army AIT trainees, and other (junior enlisted) active duty military personnel who can provide information about the risks and/or prevention of STIs, UIPs, alcohol and other substance misuse, and sexual violence within the military context. Participation will be voluntary. All potential participants will be fluent in English and able to provide written, informed consent. Our previous research and that of others show that adolescents are at increased risk for many of the health damaging behaviors and negative health outcomes that are the focus of this research.¹⁻²³ Therefore, it is important to include adolescents in this research. Since pregnant women are excluded from recruit training/AIT, none of the female volunteers will be pregnant. Active duty women who are pregnant will not be excluded from participation in the study.

4. Required Equipment and Supplies

The only equipment used for this phase of the study will be an audio tape recorder and the focus group questions that will be used by the focus group facilitators (see Attachment 7 for a copy of the focus group questions). Tape recorders will be furnished by the University of California, San Francisco.

VII. ORGANIZATION OF RESEARCH EFFORT

1. Duties and Responsibilities

Cherrie B. Boyer, PhD, Principal Investigator, will be responsible for aspects of the study. She will assist in recruiting and consenting of study participants and will co-facilitate the focus groups with Dr. Shafer. She will have overall responsibility for the analyses and interpretation of the focus group data.

Mary-Ann Shafer, MD., Co-Principal Investigator will assist Dr. Boyer in recruiting and consenting of study participants and will co-facilitate the focus groups with Dr. Boyer. She, with Dr. Boyer, will assist in the interpretation of the focus group data.

Julius Schachter, PhD, Co-Investigator, will participate in discussions on the development of the larger intervention study once all focus group data are analyzed and summarized.

CPT Lolita Burrell, PhD, Co-investigator, assisted in the development of the focus group questions and will participate in discussions on the interpretation of focus group data.

LTC Caron Wilbur, NA, Co-investigator, will participate in discussions on the interpretation of focus group data.

Allison Friedman, MS will serve primarily as an administrative research assistant to Drs. Boyer and Shafer to help facilitate the recruitment, consenting and focus group discussions. In addition, she will take primary responsibility for running the Nud*ist qualitative data software to summarize and synthesize the focus group data. She will be under the direct supervision of Drs. Boyer and Shafer.

CMDR (ret) Richard A. Shaffer, Ph.D., Project Consultant will assist all project investigators in the interpretation of

focus group results particularly the relevance to Marine Corp recruits and junior enlisted personnel. He will also consult with the project investigators on the development of the proposed interventions and self-administered questionnaires.

2. Chain of Command

All Co-Investigators and key personnel will report directly to Dr. Boyer.

VIII. RISKS AND DISCOMFORTS TO RESEARCH VOLUNTEERS

1. Risk to the Volunteer and Means of Mitigation

Risks: The risk of participating in focus group discussions are expected to be minimal. Since some of the questions will focus on risks and prevention of STDs, UIPs, alcohol and other substance misuse, and sexual violence some of the questions may be embarrassing for some of the participants, every effort will be made to minimize this possible discomfort.

Safeguards for Protecting Subjects: We will minimize potential risks for participants by first informing them that they are free to not respond to any questions that make them feel uncomfortable. Also, we will inform the participants that information discussed in the focus groups must be held in the strictest of confidence, that is, they must not share any information with anyone outside the group. It is important to note that the general purpose of the elicitation phase is to gather information that will assist in the development of pre- and post-intervention questionnaires as well as the actual interventions to reduce health damaging behaviors targeted in this research: STIs, UIPs, alcohol and other substance misuse, and sexual violence. As such, participants are encouraged to describe their general perceptions of issues related to these factors and do not necessarily have to disclose information of their specific behaviors. Additionally, military personnel who are not participating in the research will not be present during the focus group discussions. Participants will also be instructed to not name other individuals during the focus group instructions. To address the concern about participants revealing their sexual orientation, specific instructions will also be given to participants to not disclose information about their sexual activity or sexual orientation, since the military has strict policies on not disclosing such information. In our 14 years of working with military personnel around these sensitive issues, we have gained the trust of our participants and have not had a single adverse event. We have gained the reputation of civilians with interests and expertise in developing health-related programs that is created specifically for the military with input from the military.

2. Special Risks to Pregnant Women

Since pregnant women are excluded from recruit training/AIT, none of the female recruits/AIT trainees volunteering to participate in this phase of the study will be pregnant. Active duty women who are pregnant will not be excluded from participation in the focus groups. There are no special risks to pregnant women participating in focus group discussions.

3. Safety Precautions and Emergency Procedures

N/A.

4. Assessment of Sufficiency of Plans to Deal With Untoward Events or Injuries

N/A.

5. Qualification of Medical Monitor and Medical Support Personnel

N/A – Participation in this study is minimal risk.

IX. DESCRIPTION OF THE SYSTEM FOR MAINTENANCE OF RECORD

1. Experimental Data

For the elicitation phase of the study, there is some risk of the participants' loss of privacy. The participants' names and ranks will be known, but no other identifying information will be obtained. This information will be obtained on the consent and the listed rank of the active duty participants will be used only for assigning individuals to a particular focus group. As stated earlier, these groups will be conducted among individuals within the same ranks. It is important to note that the participants' names will not be used in the focus group discussions or any of the transcribed materials. Data will be reported in the aggregate. If a direct quote is used in the description of the data, only the individual's gender and military rank will be identified as the author of the quote. The focus group will involve semi-structured group interviews. See Attachment 7 for copies of focus group questions for Marine Corps recruits (male, female) and other active duty military personnel (male, female, and co-ed). Responses to the questions will be audio taped. Audio tapes will be destroyed after they are transcribed. Transcriptions of the focus group discussions will not contain any identifying information. Only study investigators and key personnel will have access to the data (paper and electronic) resulting from the focus group discussions. All data will be kept in locked files or on research computers that are password protected. Both the files and electronic data will be stored in the office of Dr. Boyer at the University of California, San Francisco.

Focus group data will be analyzed using simple content analyses as described by Krueger.²⁴ All focus groups will be audio taped. Tapes will be transcribed. Transcripts will be analyzed using Nud*ist version N6 software. Drs. Boyer, Shafer, and Shaffer, LTC Wilbur and CPT Burrell along with Ms. Friedman will review the transcripts that will be organized by question across groups (both within and across military branches) to compare and contrast all findings. Attention will be placed on identifying themes or patterns across the groups as well as themes that relate to respondents with similar demographic characteristics (e.g., gender, rank-recruit AIT trainee, non-training junior enlisted personnel). After this is completed, we will further summarize and synthesize the transcribed data using the Nud*ist software. These data will then be used to assist in the interventions' development phase, as well as in the development of pre- and post-intervention questionnaires.

2. Research Protocol, Consent Forms, and Related Documents for Protection of Human Research Volunteers

The principal investigator will keep the research protocols and consent forms in a locked files at 3333 California Street, Suite 245, Division of Adolescent Medicine, University of California, San Francisco. Electronic data will be kept in password-protected files on password-protected computers. Access to these files will be restricted to investigators and key personnel who have signed the Investigator Assurance Agreement.

3. Individual Medical Records

This research does not involve the use of medical records.

X. APPENDICES (see following page)

XI. ATTACHMENTS (included at the end of the protocol)

Attachment 1. Instructors' Introductory Script

Attachment 2. Recruitment Script

Attachment 3. Recruitment Flyer

Attachment 4. University of California, San Francisco's Experimental Subject's Bill of Rights Statement

Attachment 5. Consent Forms

Attachment 6. UCSF, Committee on Human Research, Letter of Approval

Attachment 7. Focus Group Questionnaires

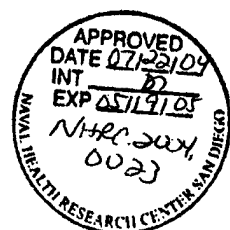
Attachment 8. Investigators' IRB Training Certificates

Attachment 9. Commanding Officers' Letters of Support

PRIVACY ACT STATEMENT

1. Authority. 5 U.S.C. 301
2. Purpose. Medical research information will be collected in an experimental research project NHRC.2004.0023 titled Preventing Health Damaging Behaviors in Army and Marine Corps Recruits to enhance basic medical knowledge, or to develop tests, procedures, and equipment to improve the diagnosis, treatment, or prevention of illness, injury, or performance impairment.
3. Routine Uses. Medical research information will be used for analysis and reports by the Departments of the Navy and Defense, and other U.S. Government agencies. Use of the information may be granted to non-Government agencies or individuals by the Navy Surgeon General following the provisions of the Freedom of Information Act or as may be indicated in the accompanying Informed Consent Form.
4. Disclosure. Provision of information is voluntary. There are no penalties for not providing the requested information but failure to provide the requested information may result in failure to be accepted as a research volunteer in an experiment, or in removal from the program.

Attached: Consent statement for this experiment, signed by the research volunteer.



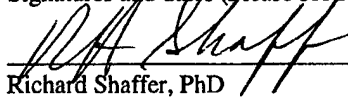
A. INVESTIGATOR ASSURANCE AGREEMENTS(s)

INVESTIGATOR ASSURANCE AGREEMENT

I, the Department Head, Principal Investigator or Co-Investigator, cited as responsible for performing and monitoring the research under the protocol titled Preventing Health Damaging Behaviors in Army and Marine Corps Recruits have read and understand the provisions of Title 32 Code of Federal Regulations Part 219 (Protection of Human Subjects), Department of Defense (DoD) Directive 3216.2 (Protection of Human Subjects in DoD-Supported Research), SECNAV Instruction 3900.39C (Protection of Human Subjects), BUMED Instruction 3900.6B (Protection of Human Subjects), and NAVHLTHRSCHCEN Instruction 3900.2B (Committee for the Protection of Human Subjects), Title 21 Code of Federal Regulations Part 50 if applicable (clinical investigations regulated by the FDA) and all relevant local instructions. I will abide by all applicable laws and regulations, and I agree that in all cases, the most restrictive regulation related to a given aspect of research involving protection of research volunteers will be followed. In the event that I have a question regarding my obligations during the conduct of this Navy-sponsored project, I have ready access to each of these regulations, as either my personal copy or available on file from the Chairperson of the Institutional Review Board. I understand that my immediate resource for clarification of any issues related to the protection of research volunteers is the Chairperson of the Institutional Review Board.

Signatures and dates (Please see following pages for other signatures):

(DD/MM/YY)


Richard Shaffer, PhD
Clinical Epidemiology

11/05/04


Cherrie B. Boyer, PhD
Principal Investigator

11/5/04

Mary-Ann Shafer, M.D.
Co-Investigator

____/____/____

Julius Schachter, PhD
Co-Investigator

____/____/____

Lolita Burrell, PhD
Co-Investigator

____/____/____

Kelli Betsinger,
Research Assistant

____/____/____

Susan Pierce
Project Assistant

____/____/____

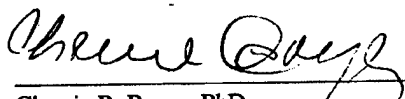
A. INVESTIGATOR ASSURANCE AGREEMENTS(s)

INVESTIGATOR ASSURANCE AGREEMENT

I, the Department Head, Principal Investigator or Co-Investigator, cited as responsible for performing and monitoring the research under the protocol titled Preventing Health Damaging Behaviors in Army and Marine Corps Recruits have read and understand the provisions of Title 32 Code of Federal Regulations Part 219 (Protection of Human Subjects), Department of Defense (DoD) Directive 3216.2 (Protection of Human Subjects in DoD-Supported Research), SECNAV Instruction 3900.39C (Protection of Human Subjects), BUMED Instruction 3900.6B (Protection of Human Subjects), and NAVHLTHRSCHCEN Instruction 3900.2B (Committee for the Protection of Human Subjects), Title 21 Code of Federal Regulations Part 50 if applicable (clinical investigations regulated by the FDA) and all relevant local instructions. I will abide by all applicable laws and regulations, and I agree that in all cases, the most restrictive regulation related to a given aspect of research involving protection of research volunteers will be followed. In the event that I have a question regarding my obligations during the conduct of this Navy-sponsored project, I have ready access to each of these regulations, as either my personal copy or available on file from the Chairperson of the Institutional Review Board. I understand that my immediate resource for clarification of any issues related to the protection of research volunteers is the Chairperson of the Institutional Review Board.

Signatures and dates (Please see following pages for other signatures):

(DD/MM/YY)


Cherrie B. Boyer, PhD
Principal Investigator

7/15/04

Mary-Ann Shafer, M.D.
Co-Investigator

____/____/____

Julius Schachter, PhD
Co-Investigator

____/____/____

CPT Lolita Burrell, PhD
Co-Investigator

____/____/____

LTC Caron Wilbur, NA
Co-Investigator

____/____/____

Allison Friedman, M.S.
Research Assistant

____/____/____

Richard A. Shaffer, Ph.D.
Project Consultant

____/____/____

B. INVESTIGATOR ASSURANCE AGREEMENTS(s)

Comment: In addition to those listed below, obtain signatures from any key support personnel (including those directly with subjects (e.g., for primary data collection/monitoring, Subject Care)). If an investigator is added to the study after the initial IRB approval, this addition must be noted in the Change Form in the Col section and on any signed Assurance Agreement with the new investigator's signature must be submitted to the IRB. Note that any individual who will be an author on publications or presentations is presumed to be an investigator and must sign an Assurance Agreement.

INVESTIGATOR ASSURANCE AGREEMENT

I, the Department Head, Principal Investigator or Co-Investigator, cited as responsible for performing and monitoring the research under the protocol titled [Protocol Title], have read and understand the provisions of Title 32 Code of Federal Regulations Part 219 (Protection of Human Subjects), Department of Defense (DoD) Directive 3216.2 (Protection of Human Subjects in DoD-Supported Research), SECNAV Instruction 3900.39C (Protection of Human Subjects), BUMED Instruction 3900.6B (Protection of Human Subjects), and NAVHLTHRSCHCEN Instruction 3900.2B (Committee for the Protection of Human Subjects), Title 21 Code of Federal Regulations Part 50 if applicable (clinical investigations regulated by the FDA) and all relevant local instructions. I will abide by all applicable laws and regulations, and I agree that in all cases, the most restrictive regulation related to a given aspect of research involving protection of research volunteers will be followed. In the event that I have a question regarding my obligations during the conduct of this Navy-sponsored project, I have ready access to each of these regulations, as either my personal copy or available on file from the Chairperson of the Institutional Review Board. I understand that my immediate resource for clarification of any issues related to the protection of research volunteers is the Chairperson of the Institutional Review Board.

Signatures and dates:


(DD/MM/YY)

[Department Head Name]
[Head of Division Name]

__/__/__

Cherrie B. Boyer, PhD
Principal Investigator

__/__/__


Mary-Ann Shafer, MD
Co-Investigator

11/5/04

Julius Schachter, PhD
Co-Investigator

__/__/__

Lolita Burrell, PhD
Co-Investigator

__/__/__

[Co-Investigator Name]
Co-Investigator

__/__/__

[Co-Investigator Name]
Co-Investigator

__/__/__

B. INVESTIGATOR ASSURANCE AGREEMENTS(s)

[Comment: In addition to those listed below, obtain signatures from any key support personnel interacting directly with subjects (e.g., recruitment, data collection, monitoring subjects, etc.). If an investigator is added to the study after the initial IRB approval, this addition must be noted in the Changes to the Protocol section, and an Investigator Assurance Agreement with the new investigator's signature must be submitted to the IRB. Note that any individual who will be an author on publications or presentations is presumed to be an investigator and must sign an assurance agreement.]

INVESTIGATOR ASSURANCE AGREEMENT

I, the Department Head, Principal Investigator or Co-Investigator, cited as responsible for performing and monitoring the research under the protocol titled [Protocol Title], have read and understand the provisions of Title 32 Code of Federal Regulations Part 219 (Protection of Human Subjects), Department of Defense (DoD) Directive 3216.2 (Protection of Human Subjects in DoD-Supported Research), SECNAV Instruction 3900.39C (Protection of Human Subjects), BUMED Instruction 3900.6B (Protection of Human Subjects), and NAVHLTHRSCHCEN Instruction 3900.2B (Committee for the Protection of Human Subjects), Title 21 Code of Federal Regulations Part 50 if applicable (clinical investigations regulated by the FDA) and all relevant local instructions. I will abide by all applicable laws and regulations, and I agree that in all cases, the most restrictive regulation related to a given aspect of research involving protection of research volunteers will be followed. In the event that I have a question regarding my obligations during the conduct of this Navy-sponsored project, I have ready access to each of these regulations, as either my personal copy or available on file from the Chairperson of the Institutional Review Board. I understand that my immediate resource for clarification of any issues related to the protection of research volunteers is the Chairperson of the Institutional Review Board.

Signatures and dates:

(DD/MM/YY)

[Program Manager Name]
[Head, Division Name]

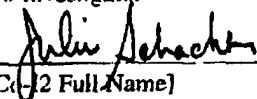
____/____/____

[PI First Name + Initials] [PI Last Name], [PI Name Degrees]
Principal Investigator

____/____/____

[Co-I1 Full Name]
Co-Investigator

____/____/____



[Co-I2 Full Name]
Co-Investigator

11/5/04

[Co-I3 Full Name]
Co-Investigator

____/____/____

[Co-I4 Full Name]
Co-Investigator

____/____/____

[Co-I5 Full Name]
Co-Investigator

____/____/____

A. INVESTIGATOR ASSURANCE AGREEMENTS(s)

INVESTIGATOR ASSURANCE AGREEMENT

I, the Department Head, Principal Investigator or Co-Investigator, cited as responsible for performing and monitoring the research under the protocol titled Preventing Health Damaging Behaviors in Army and Marine Corps Recruits have read and understand the provisions of Title 32 Code of Federal Regulations Part 219 (Protection of Human Subjects), Department of Defense (DoD) Directive 3216.2 (Protection of Human Subjects in DoD-Supported Research), SECNAV Instruction 3900.39C (Protection of Human Subjects), BUMED Instruction 3900.6B (Protection of Human Subjects), and NAVHLTHRSCHCEN Instruction 3900.2B (Committee for the Protection of Human Subjects), Title 21 Code of Federal Regulations Part 50 if applicable (clinical investigations regulated by the FDA) and all relevant local instructions. I will abide by all applicable laws and regulations, and I agree that in all cases, the most restrictive regulation related to a given aspect of research involving protection of research volunteers will be followed. In the event that I have a question regarding my obligations during the conduct of this Navy-sponsored project, I have ready access to each of these regulations, as either my personal copy or available on file from the Chairperson of the Institutional Review Board. I understand that my immediate resource for clarification of any issues related to the protection of research volunteers is the Chairperson of the Institutional Review Board.

Signatures and dates:

(DD/MM/YY)

Richard Shaffer, PhD
Clinical Epidemiology

____/____/____

Cherrie B. Boyer, PhD
Principal Investigator

____/____/____

Mary-Ann Shafer, M.D.
Co-Investigator

____/____/____

Julius Schachter, PhD
Co-Investigator

____/____/____

Lolita Burrell
Lolita Burrell, PhD
Co-Investigator

10/05/04

Kelli Betsinger,
Research Assistant

____/____/____

Susan Pierce
Project Assistant

____/____/____

A. INVESTIGATOR ASSURANCE AGREEMENTS(s)

INVESTIGATOR ASSURANCE AGREEMENT

I, the Department Head, Principal Investigator or Co-Investigator, cited as responsible for performing and monitoring the research under the protocol titled Preventing Health Damaging Behaviors in Army and Marine Corps Recruits have read and understand the provisions of Title 32 Code of Federal Regulations Part 219 (Protection of Human Subjects), Department of Defense (DoD) Directive 3216.2 (Protection of Human Subjects in DoD-Supported Research), SECNAV Instruction 3900.39C (Protection of Human Subjects), BUMED Instruction 3900.6B (Protection of Human Subjects), and NAVHLTHRSCHCEN Instruction 3900.2B (Committee for the Protection of Human Subjects), Title 21 Code of Federal Regulations Part 50 if applicable (clinical investigations regulated by the FDA) and all relevant local instructions. I will abide by all applicable laws and regulations, and I agree that in all cases, the most restrictive regulation related to a given aspect of research involving protection of research volunteers will be followed. In the event that I have a question regarding my obligations during the conduct of this Navy-sponsored project, I have ready access to each of these regulations, as either my personal copy or available on file from the Chairperson of the Institutional Review Board. I understand that my immediate resource for clarification of any issues related to the protection of research volunteers is the Chairperson of the Institutional Review Board.

Signatures and dates (Please see following pages for other signatures):

(DD/MM/YY)

Cherrie B. Boyer, PhD
Principal Investigator

____/____/____

Mary-Ann Shafer, M.D.
Co-Investigator

____/____/____

Julius Schachter, PhD
Co-Investigator

____/____/____

CPT Lolita Burrell, PhD
Co-Investigator

____/____/____

Caron Wilbur

LTC Caron Wilbur, M.S.
Co-Investigator

19 07 2004

Allison Friedman, M.S.
Research Assistant

____/____/____

Richard A. Shaffer, Ph.D.
Project Consultant

____/____/____

Version Date: 09 July 2004

A-1

A. INVESTIGATOR ASSURANCE AGREEMENTS(s)

INVESTIGATOR ASSURANCE AGREEMENT

I, the Department Head, Principal Investigator or Co-Investigator, cited as responsible for performing and monitoring the research under the protocol titled Preventing Health Damaging Behaviors in Army and Marine Corps Recruits have read and understand the provisions of Title 32 Code of Federal Regulations Part 219 (Protection of Human Subjects), Department of Defense (DoD) Directive 3216.2 (Protection of Human Subjects in DoD-Supported Research), SECNAV Instruction 3900.39C (Protection of Human Subjects), BUMED Instruction 3900.6B (Protection of Human Subjects), and NAVHLTHRSCHCEN Instruction 3900.2B (Committee for the Protection of Human Subjects), Title 21 Code of Federal Regulations Part 50 if applicable (clinical investigations regulated by the FDA) and all relevant local instructions. I will abide by all applicable laws and regulations, and I agree that in all cases, the most restrictive regulation related to a given aspect of research involving protection of research volunteers will be followed. In the event that I have a question regarding my obligations during the conduct of this Navy-sponsored project, I have ready access to each of these regulations, as either my personal copy or available on file from the Chairperson of the Institutional Review Board. I understand that my immediate resource for clarification of any issues related to the protection of research volunteers is the Chairperson of the Institutional Review Board.

Signatures and dates:

(DD/MM/YY)

Richard Shaffer, PhD
Clinical Epidemiology

//_

Cherrie B. Boyer, PhD
Principal Investigator

//_

Mary-Ann Shafer, M.D.
Co-Investigator

//_

Julius Schachter, PhD
Co-Investigator

//_

Kelli Betsinger

Kelli Betsinger,
Research Assistant

5/8/04

Susan Pierce

Susan Pierce
Project Assistant

11/5/04

A. INVESTIGATOR ASSURANCE AGREEMENTS(s)

INVESTIGATOR ASSURANCE AGREEMENT

I, the Department Head, Principal Investigator or Co-Investigator, cited as responsible for performing and monitoring the research under the protocol titled Preventing Health Damaging Behaviors in Army and Marine Corps Recruits have read and understand the provisions of Title 32 Code of Federal Regulations Part 219 (Protection of Human Subjects), Department of Defense (DoD) Directive 3216.2 (Protection of Human Subjects in DoD-Supported Research), SECNAV Instruction 3900.39C (Protection of Human Subjects), BUMED Instruction 3900.6B (Protection of Human Subjects), and NAVHLTHRSCHCEN Instruction 3900.2B (Committee for the Protection of Human Subjects), Title 21 Code of Federal Regulations Part 50 if applicable (clinical investigations regulated by the FDA) and all relevant local instructions. I will abide by all applicable laws and regulations, and I agree that in all cases, the most restrictive regulation related to a given aspect of research involving protection of research volunteers will be followed. In the event that I have a question regarding my obligations during the conduct of this Navy-sponsored project, I have ready access to each of these regulations, as either my personal copy or available on file from the Chairperson of the Institutional Review Board. I understand that my immediate resource for clarification of any issues related to the protection of research volunteers is the Chairperson of the Institutional Review Board.

Signatures and dates (Please see following pages for other signatures):

(DD/MM/YY)

Cherrie B. Boyer, PhD
Principal Investigator

____/____/____

Mary-Ann Shafer, M.D.
Co-Investigator

____/____/____

Julius Schachter, PhD
Co-Investigator

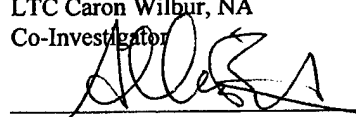
____/____/____

CPT Lolita Burrell, PhD
Co-Investigator

____/____/____

LTC Caron Wilbur, NA
Co-Investigator

____/____/____



Allison Friedman, M.S.
Research Assistant

09/15/04

Richard A. Shaffer, Ph.D.
Project Consultant

____/____/____

B. REVIEW FOR PROTECTION OF HUMAN RESEARCH VOLUNTEERS

1. Recommendation(s) of the Institutional Review Board (IRB)
2. Minutes of the Meeting of the IRB
3. Recommendation of the Convening Authority
4. Action of the Approving Authority
5. Other Documentation (as required)

- a. Unlabeled use of approved drugs or licensed biologics: N/A

Provide documentation from the Food and Drug Administration (FDA) authorizing exemption from the requirement for Investigational New Drug Application (IND): N/A

- b. Experimental drugs, biologics or devices: N/A

- i. Documentation of approved IND or Investigational Device Exemption (IDE) from the FDA

- ii. Approval of the Naval Investigational Drug Review Board (NIDRB)

- c. Documentation of review and action taken by all collaborating institution(s)

- i. Acceptable results of review are: approval, exemption from review, joint review, or other formal review agreement

See Attachment 6 for a copy the University of California, San Francisco, Committee on Human Research's approval of the elicitation phase of the study.

We are seeking simultaneous approval from the Brooke Army Medical Center IRB (the oversight committee for the 32nd Medical Brigade) and secondary approval from the Human Subjects Research Review Board at the Fort Detrick (our funding institution).

- ii. Certification by the principal investigator that protocol submitted for review is the same final copy approved or under simultaneous review by collaborating institution(s):

The materials submitted to IRBs at Brooke Army Medical Center is the same as those submitted in this application. Modifications made in the preparation of this application will be submitted to the University of California, San Francisco, Committee on Human Research and the Human Subjects Research Board at Fort Detrick will be submitted after final approval of this application. Letters of approval will be submitted to the Naval Health Research Center's IRB committee once they are received.

- d. Host Government Approval if Research Is Performed in a Foreign Country: N/A

- e. Legal Issues: N/A

- i. Sufficiency of third party permission

1. Citation of statutory authority

2. IRB determination regarding requirement for assent

- ii. Citation of statutory authority for compensation of volunteers

iii. Other

- f. OPNAV Form 5214-10 (if required for questionnaire survey include CNO approval document)

Copies of the Focus Group Questionnaires are listed in Attachment 7.

- g. Request for waiver of requirement(s) for protection of human research volunteers: N/A
- h. Documentation of exemption from compliance with regulations for the protection of human research volunteers (State authority and criteria for exemption): N/A
- i. Other

C. POSTAPPROVAL DOCUMENTATION: N/A

1. Change of investigator(s), medical monitor, or collaborating institution(s) (addition or deletion)
2. Significant modification(s) to the protocol
3. IRB continuing review (annually)
 - a. Reviewed by BUMED activity
 - b. Review by collaborating institution(s)
 - c. Modification of IRB recommendations
4. Documentation of all official action since initial submission and review

D. SPECIAL REPORTS: N/A

1. Unanticipated complications or problems
2. Reports of noncompliance with requirements for protection of human research volunteers
3. Adverse IRB action
 - a. Recommendation for suspension
 - b. Recommendation for termination
4. Resulting action by convening and approving authorities

E. REFERENCES

1. Boyer CB, Shafer MA, Shaffer RA, et al. Prevention of sexually transmitted diseases and HIV in young military men: evaluation of a cognitive-behavioral skills-building intervention. *Sexually Transmitted Diseases*. 2001;28:349-355.
2. Boyer CB, Shafer MA. Preventing STDs and unplanned pregnancies: a cognitive-behavioral intervention for young women entering the U.S. military. *Journal of Adolescent Health*. 2003;32(2):129.
3. Gaydos CA, Howell MR, Pare B, al. e. *Chlamydia trachomatis* infections in female military recruits. *NEJM*. 1998;339:739-744.
4. Boyer CB, Shafer MA, Moncada J, Schachter J, Shaffer RA, Brodine SK. Sociodemographic, behavioral, and clinical factors associated with STDs in a national sample of women entering the US military. *ISSTD: Sexually Transmitted Infections*. 2001:241-246.
5. Shafer MA, Moncada J, Boyer CB, Betsinger K, Flinn SD, Schachter J. Comparing the FVU, self-collected vaginal swabs and endocervical specimens to detect *C. trachomatis* and *N. gonorrhoeae* using Nucleic Acid Amplification Tests. *Submitted*. 2003.
6. CDC. *Sexually Transmitted Disease Surveillance 2000*. Atlanta, GA: Division of Sexually Transmitted Diseases, National Center for HIV, STD and TB Prevention; 2001.
7. Cecil JA, Howell MR, Tawes JJ, Gaydos JC, McKee KT. Features of *C. trachomatis* and *N. gonorrhoeae* in male army recruits. *Journal of Infectious Diseases*. 2001;184:1216-1219.
8. Brodine SK, Shafer MA, Shaffer RA, et al. Asymptomatic sexually transmitted disease prevalence in four military populations: Application of DNA amplification assays for chlamydia and gonorrhea screening. *Journal of Infectious Diseases*. 1998;178:1202-1204.
9. Shafer MA, Boyer CB, Shaffer RA, Schachter J, Ito SI, Brodine SK. Correlates of STDs in a young male deployed military population. *Military Medicine*. 2002;167:496-500.
10. Yen S, Shafer MA, Moncada J, Campbell CJ, Flinn SD, Boyer CB. Prevalence of clinical correlates of bacterial vaginosis among sexually experienced and non-sexually experienced young women entering the military. *Submitted* 2003.
11. Shafer MA, Pantell R, Schachter J. Is the routine pelvic examination needed with the advent of urine-based screening for sexually transmitted diseases? *Archives of Pediatric and Adolescent Medicine*. 1999;153:119-125.
12. Howell MR, Gaydos JC, McKee KT, Quinn TC, Gaydos CA. Control of *Chlamydia trachomatis* infections in female army recruits: cost-effective screening and treatment in training cohorts to prevent pelvic inflammatory disease. *Sexually Transmitted Diseases*. 1999;26:519-526.
13. Magann EF, Nolan TE. Pregnancy outcome in an active-duty population. *Obstetrics and Gynecology*. 1992;79:157.
14. McNeary AM, Lomenick TS. Military duty: risk factor for preterm labor? *Military Medicine*. 2000;165:612-615.
15. Clark JB, Holt VL, Miser F. Unintended pregnancy among female soldiers presenting for prenatal care at Madigan Army Medical Center. *Military Medicine*. 1998;163:444-448.
16. United States Department of Health and Human Services. *Alcohol research & health: highlights from the tenth special report to Congress, Health risks and benefits of alcohol consumption*. vol 24. Washington, DC: U.S. Government Printing Office; 2000.
17. Bray RM, Fairbank JA, Marsden ME. Stress and substance use among military women and men. *American Journal of Drug and Alcohol Abuse*. 1999;25:239-256.
18. Martin L, Rosen LN, Durand DB, Stretch RH, Knudson KH. Prevalence and timing of sexual assaults in a sample of male and female U.S. Army soldiers. *Military Medicine*. 1998;163:213-216.
19. Martin L. Personality characteristics that increase vulnerability to sexual harassment among U.S. Army soldiers. *Military Medicine*. 2000;165:709-713.
20. Sadler AG, Booth BM, Cook BL, Doebbeling BN. Factors associated with women's risk of rape in the military environment. *American Journal of Industrial Medicine*. 2003;43:262-273.
21. Sadler AG, Booth BM, Nielson D, Doebbeling BN. Health-related consequences of physical and sexual violence: women in the military. *Obstetrics and Gynecology*. 2000;96:473-480.
22. Jemmott III JB, Jemmott LS, Fong GT. Abstinence and safer sex HIV risk-reduction interventions for

- African American adolescents: a randomized controlled trial. *Journal of the American Medical Association*. 1998;279:1529-1536.
23. National Institute of Mental Health. The NIMH multisite HIV prevention trial: reducing HIV sexual risk behavior. *Science*. 1998;280:1889-1894.
 24. Shain RN, Piper JA, Newton ER, et al. A randomized controlled trial of a behavioral intervention to prevent sexually transmitted disease among minority women. *N Engl J Med*. 1999;340:93-100.
 25. Boyer CB, Barrett DC, Peterman TA, Bolan G. STD and HIV risk in heterosexual adults attending a public STD clinic: evaluation of a randomized, controlled, behavioral risk reduction intervention trial. *AIDS*. 1997;11:359-367.
 26. Boyer CB, Shafer MA, Tschann J. Evaluation of a knowledge and cognitive-behavioral skills building intervention to prevent STDs and HIV infection in high school students. *Adolescence*. 1997;32(125):25-42.
 27. Jenkins RA, Jenkins PR, Nannis ED, McKee Jr KT, Temoshok LR. Correlates of human immunodeficiency virus infections to risk behavior in male attendees of a clinic for sexually transmitted disease. *Clin Infect Dis*. 2000;30:723-729.
 28. Williams JO, Bell NS, Amoroso PJ. Drinking and other risk taking behaviors of enlisted male soldiers in the US Army. *Work*. 2002;18:141-150.
 29. Ehrhardt AA, Exner TM. Prevention of sexual risk behavior for HIV infection with women. *AIDS*. 2000;14(Suppl 2):S53-58.
 30. Wingood GM, DiClemente RJ. HIV sexual risk reduction interventions for women: a review. *American Journal of Preventive Medicine*. 1996;12(3):209-217.
 31. Fisher JD, Fisher WA, Williams SS, Malloy TE. Empirical tests of an Information- Motivation-Behavioral skills model of AIDS-preventive behavior with gay men and heterosexual university students. *Health Psychol*. 1994;13:238-250.

F. NONTECHNICAL SYNOPSIS

The overall purpose of the proposed research is to: (1) prevent sexually transmitted infections (STIs), unintended pregnancies (UIPs), alcohol and other substance misuse, and exposure to or involvement with sexual violence in military personnel; (2) reduce military personnel's risk for STIs, UIPs, alcohol and other substance misuse, and exposure to or involvement with sexual violence and; (3) determine the best strategy for educating military personnel about sensitive health matters such as STIs, UIPs, alcohol and other substance misuse, and exposure to or involvement with sexual violence.

The goal of the elicitation phase of this study is to conduct focus groups to develop: (1) separate gender- and branch-specific interventions to reduce health damaging behaviors associated with STIs, UIPs, alcohol and other substance misuse, and sexual violence; and (2) pre- and post-intervention, self-administered, questionnaires to assess knowledge, attitudes, and beliefs, and behaviors of the target groups.

Approximately 168 persons (84 from Fort Sam Houston, 32nd Medical Brigade and 84 from the Marine Corps Recruiting Depot, SC) will participate in focus group discussions. A total of 24 co-ed and gender-segregated focus groups will be conducted with AIT students and junior enlisted personnel, 12 of which will come from Fort Sam Houston. We will determine which platoon/class will participate in same-gender discussions and which platoons will participate in co-ed discussions using a random assignment table of odd and even numbers. For example, all platoons/class will be listed in a random order and assigned an odd or even number a priori. All even-numbered platoons/class will be assigned to co-ed discussions and all odd-numbered platoons will be assigned to separate same-gendered discussions. Specifically, for Army AIT trainees, we will conduct two co-ed focus groups, two focus groups with males, and two focus groups with females (for a total of six focus groups among Army AIT trainees). For junior enlisted Army personnel there will be two male and two female group and two co-ed groups (for a total of six junior enlisted groups).

ATTACHMENTS

1. Instructors' Introductory Script
2. Recruitment Script
3. Recruitment Flyer
4. University of California, San Francisco's
Experimental Subject's Bill of Rights Statement
5. Marine Corps Consent Forms
6. UCSF, Committee on Human Research, Letter of
Approval
7. Marine Corps Focus Group Questionnaires
8. Investigators' IRB Training Certificates
9. Commanding Officers' Letters of Support

Attachment 1.

Instructors' Introductory Script

INSTRUCTORS' INTRODUCTORY SCRIPT
(for Marine Corps Recruits and AIT Trainees)

Today, we have researchers from the University of California, San Francisco who will give you information on a new program they are developing specifically for the military. They are looking for volunteers to discuss some of the issues they will address in the program. They are here to tell you more about the program. Please give them your undivided attention.



Attachment 2.

Recruitment Script

RECRUITMENT SCRIPT

Good Morning (Afternoon). I am Dr. Boyer and this is my colleague(s) (state name(s) of colleague(s)). We are researchers from the University of California, San Francisco and we have been funded by the Department of Defense to address issues that concern of young Marines/soldiers including the risk of sexually transmitted diseases such as chlamydia and gonorrhea, unintended pregnancies (that is pregnancies that were not planned), alcohol use and abuse, and sexual harassment as well as sexual violence. We have been working on these very important health issues for over 20 years (for Dr. Shafer for nearly 30 years). However, over the last 14 years we have worked with young military recruits and junior enlisted military personnel to help prevent these health problems. Our main interest is prevention. We have developed videos and educational programs that were developed with the help of young men and women Marines and soldiers such as you. These materials have been well received because we developed them with the help and insight of those we hope that will benefit from the information provided in the programs.

The reason we are here today is to ask for volunteers to spend about two hours with us to help us better understand health issues such as STDs, alcohol use, and sexual harassment and sexual violence and other health concerns that young Marines/soldiers may have. This two-hour group discussion will take place (indicate time/location) during your regularly scheduled class period (for recruits/AIT trainees)/during the work-day (for other junior enlisted personnel). I want to emphasize that you are not obligated to participate, we are looking for volunteers. If you choose



not to participate, it will not have any impact (positive or negative) on your training (career for non-training personnel).

In the group discussion we will not use your names or any other information that may identify you. We will not ask about your personal behaviors. We are particularly interested in your views and opinions. There are no right or wrong answers, but rather differing points of view. By participating in this discussion you will have an opportunity to help shape the development of programs that may help young Marines/soldiers that will come behind you.

Sensitive topics will be discussed and may make some people feel uncomfortable. As stated earlier, it is important that you do not mention names of any of other person during the focus group discussion. It is also important that you do not reveal any personal information, as there is no guarantee that what you say will not be repeated outside this room by other participants.

Revealing confidential information could lead to embarrassment and possible disciplinary actions under the Uniform Code of Military Justice.

If you are interested, please give us one of the placards that contain the number given to you when you entered the room. We will randomly select up to seven individuals to participate in each discussion. Pizza and beverages will be served.**

**Note: Pizza, soda, juice and water will be provided for all other participants. For Recruits, juice and water (and pizza) will be provided to recruits only if it is allowed by the Drill Instructors.



Attachment 3.

Recruitment Flyer

SEXUALLY TRANSMITTED DISEASES SEXUAL HARASSMENT ALCOHOL

**THESE ARE ISSUES THAT CONFRONT
YOUNG ADULTS**

You have an opportunity to discuss your point of view on these issues and help to develop a program that will address concerns of young Marines.

Researchers from the University of California, San Francisco will be giving a brief on a program they will develop to address these important issues in the military.

**THEY ARE LOOKING FOR VOLUNTEERS TO PARTICIPATE
IN A TWO-HOUR GROUP DISCUSSION THAT WILL TAKE
PLACE DURING WORK-HOURS
(PIZZA AND SODA WILL BE SERVED)**

You have an opportunity to give your opinions and point of view that will help in the development of this health program.

If you are interested, come to a 15-minute brief (*add time and location here*) to learn more about the program and more about the group discussion.



Attachment 4.

**University of California, San Francisco's
Experimental Subject's Bill of Rights Statement**

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
EXPERIMENTAL SUBJECT'S
BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject I have the following rights:

- 1) To be told what the study is trying to find out,
- 2) To be told what will happen to me and whether any of the procedures, drugs, or devices is different from what would be used in standard practice,
- 3) To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me for research purposes,
- 4) To be told if I can expect any benefit from participating, and, if so, what the benefit might be,
- 5) To be told of the other choices I have and how they may be better or worse than being in the study,
- 6) To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study,
- 7) To be told what sort of medical treatment is available if any complications arise,
- 8) To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my right to receive the care I would receive if I were not in the study,
- 9) To receive a copy of the signed and dated consent form,
- 10) To be free of pressure when considering whether I wish to agree to be in the study.

If I have other questions I should ask the researcher or the research assistant. In addition, I may contact the Committee on Human Research, which is concerned with protection of volunteers in research projects. I may reach the committee office by calling: (415) 476-1814 from 8:00 AM to 5:00 PM, Monday to Friday, or by writing to the Committee on Human Research, Box 0962, University of California, San Francisco, CA 94143.

Call 476-1814 for information on translations.

12/91



Attachment 5.

Marine Corps Consent Forms

1. Marine Corps Junior Enlisted Consent Form
2. Marine Corps Recruits' Consent Form

**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO BE A RESEARCH SUBJECT**

Preventing Health Damaging Behaviors and Negative Health Outcomes in Army and Marine Corps Personnel During Their First Tour of Duty

Marine Corps Junior Enlisted Consent Form

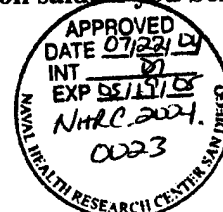
A. PURPOSE AND BACKGROUND

Cherrie B. Boyer, PhD and Mary-Ann Shafer from the Department of Pediatrics, Division of Adolescent Medicine at the University of California, San Francisco, LTC Caron Wilbur, AN from the 32nd Medical Brigade at Fort Sam Houston and CPT Lolita Burrell from the USARIEM/WAMC are conducting a research study to prevent and reduce the risk of sexually transmitted infections, unintended pregnancies, alcohol and other substance misuse, and exposure to or involvement with sexual violence among Army and Marine Corps personnel during their first tour of duty. To accomplish this goal, we will develop and implement interventions for recruits and junior enlisted personnel in both branches of the military. In order to develop the interventions, we will conduct focus groups to gather information regarding Marines' risk for sexually transmitted infections, unintended pregnancies, alcohol and other substance misuse, and sexual violence. This study is being funded by the Department of Defense, Army Medical and Material Command at Fort Detrick Maryland. You are being asked to participate in this study because you are in the Marine Corps and may be able to provide information on factors that both protect and place young Marines at risk for health outcomes such as sexually transmitted infections, unintended pregnancies, alcohol and other substance misuse, and sexual violence. Participation in this study is voluntary, that is, you are free to decline participation without having a negative impact on you or your military career.

B. PROCEDURES

If you agree to be in the study, the following will occur:

1. You will participate in a single two-hour focus group discussion with other military personnel within your ranks. Overall, there will be two male and two female groups and two co-ed groups (for a total of six groups). These groups will be conducted among individuals within the same ranks. Each focus group will consist of 5-7 participants. However, there will be approximately 168 individuals participating in focus groups overall.
2. During the focus group discussion names or other personal identifying information will not be used. You and other members of the group will be asked to discuss your knowledge, attitudes, and beliefs about the risk and prevention of sexually transmitted infections, unintended pregnancies, alcohol and other substances, and sexual violence among young men and women in your age group. We will not be asking you to disclose personal behaviors related to these health issues. We are only interested in you providing your general perceptions about health behaviors among your peers, especially those in your groups. **It is important that you do NOT mention any names of other personnel during these focus group discussions. It is also important that you do NOT tell others outside this room what a specific person said. If you believe you**



cannot adhere to these two requirements, please inform the focus group facilitator immediately. It is also important not to reveal any personal information as there is no guarantee that what you say will not be repeated outside this room by other participants/ Revealing confidential information could lead to embarrassment and possible disciplinary actions under the Uniform Code of Military Justice.

3. An audiotape will be made of this discussion.
4. The focus groups will be lead by Drs. Boyer and Shafer or their civilian research assistants. Drill Instructors or any other military personnel will not be present during these discussions.
5. Your names will not be used during the focus group discussion or any of the summaries of the discussions.
6. This information will be used to develop the best possible intervention program for young Marines during their first tour of duty.
7. The focus groups will take place in a classroom on base.

C. RISKS/DISCOMFORTS

1. Some of the focus group discussion questions may make you uncomfortable or may be embarrassing, but you are free to decline to answer any questions you do not wish to answer or to leave the group at any time. It is also important for you to not repeat information outside of the discussion in the group.
2. Participation in research may involve a loss of privacy; however, the audio tapes and transcripts of the focus groups will be handled as confidentially as possible. The researchers will ask you and the other participants to not use names during the group session. They will also ask group members not to tell anyone outside the group what any particular person said in the group. However, the researchers cannot guarantee that everyone will keep the discussions private. Only Dr. Boyer, Dr. Shafer and their assistants will have access to the audiotapes and transcripts of the tapes. After the group discussion has been transcribed from the tapes, the tapes will be destroyed. No individual identities will be used in any reports or publications that may result from this study.

D. BENEFITS

There will be no direct benefit to you from participating in this study. However, the information that you provide may help us develop the most effective intervention to prevent health problems such as sexually transmitted infections, unplanned pregnancies, alcohol and other substance misuse, and sexual violence for young Marines.

E. COSTS

There will be no costs to you as a result of taking part in this study.



F. PAYMENT

You will not be paid for participation in this study.

G. QUESTIONS

You have talked to Dr. Boyer, Dr. Shafer, or the person who signed below about this study and have had your questions answered. If you have further questions, you may call them at (415) 514-3672.

If you have any comments or concerns about participation in this study, you should first talk with Dr. Boyer or Dr. Shafer. If for some reason you do not wish to do this, you may contact the Committee on Human Research, which is concerned with the protection of volunteers in research projects. You may reach the committee office between 8:00 and 5:00, Monday through Friday, by calling (415) 476-1814, or by writing: Committee on Human Research, Box 0962, University of California, San Francisco, San Francisco, CA 94143. Alternatively, if you have questions about your rights as a research participant you may contact Christopher Blood, JD, MA of the Naval Health Research Center at (619) 553-8386 or blood@nhrc.navy.mil.

H. CONSENT

You have been given a copy of the "Human Subjects Bill of Rights" statement and will also be given a copy of this consent form and a privacy act statement to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You are free to decline to be in this study, or to withdraw from it at any point. Your decision as to whether or not to participate in this study will have no influence on your military career.

If you agree to participate you should sign below.

Date

Signature of Study Participant

Date

Signature of Person Obtaining Consent



**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO BE A RESEARCH SUBJECT**

Preventing Health Damaging Behaviors and Negative Health Outcomes in Army and Marine Corps Personnel During Their First Tour of Duty

Marine Corps Recruits' Consent Form

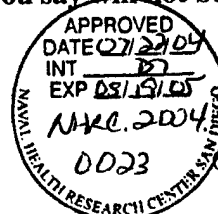
A. PURPOSE AND BACKGROUND

Cherrie B. Boyer, PhD and Mary-Ann Shafer from the Department of Pediatrics, Division of Adolescent Medicine at the University of California, San Francisco, LTC Caron Wilbur, AN from the 32nd Medical Brigade at Fort Sam Houston and CPT Lolita Burrell from the USARIEM/WAMC are conducting a research study to prevent and reduce the risk of sexually transmitted infections, unintended pregnancies, alcohol and other substance misuse, and exposure to or involvement with sexual violence among Army and Marine Corps personnel during their first tour of duty. To accomplish this goal, we will develop and implement interventions for recruits and junior enlisted personnel in both branches of the military. In order to develop the interventions, we will conduct focus groups to gather information regarding Marines' risk for sexually transmitted infections, unintended pregnancies, alcohol and other substance misuse, and sexual violence. This study is being funded by the Department of Defense, Army Medical and Material Command at Fort Detrick Maryland. You are being asked to participate in this study because you are currently in recruit training at MCRD on Parris Island. Participation in this study is voluntary, that is, you are free to decline participation without having a negative impact on you or your military training.

B. PROCEDURES

If you agree to be in the study, the following will occur:

1. You will participate in a single two-hour focus group discussion with other recruits from your platoon. Focus groups will be conducted separately for males and females since your platoons are separated by gender. Overall, there will be three separate focus groups with female Marine Corps recruits and three with males (for a total of six focus groups). Each focus group will consist of 5-7 participants. However, there will be approximately 168 individuals participating in focus groups overall.
2. During the focus group discussion names or other personal identifying information will not be used. You and other members of the group will be asked to discuss your knowledge, attitudes, and beliefs about the risk and prevention of sexually transmitted infections, unintended pregnancies, alcohol and other substances, and sexual violence among young men and women in your age group. We will not be asking you to disclose personal behaviors related to these health issues. We are only interested in you providing your general perceptions about health behaviors among your peers, especially those in your groups. **It is important that you do NOT mention any names of other personnel during these focus group discussions. It is also important that you do NOT tell others outside this room what a specific person said. If you believe you cannot adhere to these two requirements, please inform the focus group facilitator immediately. It is also important not to reveal any personal information as there is no guarantee that what you say will not be**



repeated outside this room by other participants/ Revealing confidential information could lead to embarrassment and possible disciplinary actions under the Uniform Code of Military Justice.

3. An audiotape will be made of this discussion.
4. The focus groups will be lead by Drs. Boyer and Shafer or their civilian research assistants. Drill Instructors or any other military personnel will not be present during these discussions.
5. Your names will not be used during the focus group discussion or any of the summaries of the discussions.
6. This information will be used to develop the best possible intervention program for young Marines during their first tour of duty.
7. The focus groups will take place in a classroom on base.

C. RISKS/DISCOMFORTS

1. Some of the focus group discussion questions may make you uncomfortable or may be embarrassing, but you are free to decline to answer any questions you do not wish to answer or to leave the group at any time. It is also important for you to not repeat information outside of the discussion in the group.
2. Participation in research may involve a loss of privacy; however, the audio tapes and transcripts of the focus groups will be handled as confidentially as possible. The researchers will ask you and the other participants to not use names during the group session. They will also ask group members not to tell anyone outside the group what any particular person said in the group. However, the researchers cannot guarantee that everyone will keep the discussions private. Only Dr. Boyer, Dr. Shafer and their assistants will have access to the audiotapes and transcripts of the tapes. After the group discussion has been transcribed from the tapes, the tapes will be destroyed. No individual identities will be used in any reports or publications that may result from this study.

D. BENEFITS

There will be no direct benefit to you from participating in this study. However, the information that you provide may help us develop the most effective intervention to prevent health problems such as sexually transmitted infections, unplanned pregnancies, alcohol and other substance misuse, and sexual violence for young Marines.

E. COSTS

There will be no costs to you as a result of taking part in this study.

F. PAYMENT

You will not be paid for participation in this study.



G. QUESTIONS

You have talked to Dr. Boyer, Dr. Shafer, or the person who signed below about this study and have had your questions answered. If you have further questions, you may call them at (415) 514-3672.

If you have any comments or concerns about participation in this study, you should first talk with Dr. Boyer or Dr. Shafer. If for some reason you do not wish to do this, you may contact the Committee on Human Research, which is concerned with the protection of volunteers in research projects. You may reach the committee office between 8:00 and 5:00, Monday through Friday, by calling (415) 476-1814, or by writing: Committee on Human Research, Box 0962, University of California, San Francisco, San Francisco, CA 94143. Alternatively, if you have questions about your rights as a research participant you may contact Christopher Blood, JD, MA of the Naval Health Research Center at (619) 553-8386 or blood@nhrc.navy.mil.

H. CONSENT

You have been given a copy of the "Human Subjects Bill of Rights" statement and will also be given a copy of this consent form and a privacy act statement to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You are free to decline to be in this study, or to withdraw from it at any point. Your decision as to whether or not to participate in this study will have no influence on your military career.

If you agree to participate you should sign below.

Date

Signature of Study Participant

Date

Signature of Person Obtaining Consent



Attachment 6.

**University of California, San Francisco,
Committee on Human Research,
Letter of Approval**

CHR APPROVAL LETTER

TO: Cherrie Boyer, Ph.D.
Box 0503

Mary-Ann Shafer, M.D.
Box 0503,

RE Preventing Health Damaging Behaviors and Negative Health Outcomes in Army and Marine Corps Personnel During their First Tour of Duty

The Committee on Human Research (CHR) has reviewed and approved this application to involve humans as research subjects. This included a review of all documents attached to the original copy of this letter.

Specifically, the review included but was not limited to the following documents:

4 Consent Forms, dated 10/24/03

Army Junior Enlisted Consent Form, dated 1/27/04; Army Recruits' Consent Form, dated 1/27/04

Marine Corps Junior Enlisted Consent Form, dated 1/27/04; Marine Corps Recruits' Consent Form, dated 1/27/04

The CHR is the Institutional Review Board (IRB) for UCSF and its affiliates. UCSF holds Office of Human Research Protections Federalwide Assurance number FWA00000068. See the CHR website for a list of other applicable FWA's.

APPROVAL NUMBER: H7183-24127-01. This number is a UCSF CHR number and should be used on all correspondence, consent forms and patient charts as appropriate.

APPROVAL DATE: January 28, 2004.

Full Committee Review

EXPIRATION DATE: January 28, 2005. If the project is to continue, it must be renewed by the expiration date.

GENERAL CONDITIONS OF APPROVAL: Please refer to www.ucsf.edu/ora/chr/gen_cond_appvl.htm for a description of the general conditions of CHR approval. In particular, please note that prior CHR approval is required before implementing any changes in the consent documents or any changes in the protocol unless those changes are required urgently for the safety of the subjects.

QUESTIONS: Please contact the office of the Committee on Human Research at (415) 476-1814 or campus mail stop, Box 0962, or by electronic mail at chr@research.ucsf.edu.

Sincerely,



Victor I. Reus, M.D.
Chair
Committee on Human Research

cc: Susan Pierce, Box 0503

Attachment 7.

Marine Corps Focus Group Questionnaires

1. Co-Ed Junior Enlisted Marines
2. Female Junior Enlisted Marines
3. Male Junior Enlisted Marines
4. Female Marine Corps Recruits
5. Male Marine Corps Recruits

*Preventing Health Damaging Behaviors and Negative Health Outcomes in Army and Marine Corps
Personnel During Their First Tour of Duty*

FOCUS GROUP WITH CO-ED JUNIOR ENLISTED MARINES

Welcome, and thank you for agreeing to participate in our group discussion. The purpose of this discussion is to learn about the risk and prevention of sexually transmitted infections, unintended pregnancies, alcohol and other substance misuse, and sexual violence in Marines during their first tour of duty.

I am _____ and I am a _____ from the University of California, San Francisco. Also with me today is my colleague _____ also from the University of California, San Francisco. I will let her introduce herself to you. We are collaborating on a research project to determine effective and creative ways of reducing the risk and preventing negative health outcomes in male and female Marines during their first tour of duty.

The reason you were asked to participate in this discussion today is to provide us with first-hand information about what you see as the most important issues which threaten the health and military readiness of young Marines. We are particularly interested in your views and opinions. There are no right or wrong answers, but rather differing points of view. Please feel free to share your point of view even if it differs from what others have said. Also, it is important that you do NOT mention any names of other personnel during these focus group discussions. It is also important that you do NOT tell others outside this room what a specific person said. If you believe you cannot adhere to these two requirements, please inform the focus group facilitator immediately. It is also important not to reveal any personal information as there is no guarantee that what you say will not be repeated outside this room by other participants/ Revealing confidential information could lead to embarrassment and possible disciplinary actions under the Uniform Code of Military Justice.

Before we begin, I would like to make a few points about how we will run this session:

- (1) The information you provide to us will be utilized to develop health promotion interventions for Marine Corps recruits.
- (2) The information you provide in this group is confidential; names will not be used in any summary of this discussion.
- (3) Please keep in mind that we are just as interested in the negative comments as the positive comments, and many times the negative comments are the most helpful.
- (4) Our session today will last about two hours and we will not be taking a formal break.

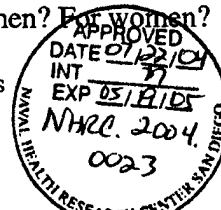


General Perceptions

1. Why do you think young people choose to join the Marine Corps?
2. After recruit training, what do think are the most stressful things about being a young Marine? (Career/job? Personal life?)
3. Some people think that many young people in the military get married much younger than their same-age peers who are not in the military. Do you share that perception? Why do you think this is (is not) the case?

Risk Factors

4. Can you tell me your perceptions about social situations for Marines after MCT training (during service school)? Do you think the experiences are the same or different for men and women? In what ways are they the same and in what ways are they different?
5. Can you describe the social situations for Marines living in barracks during service school training?
6. Some research indicates that reasons why young people engage in risk behaviors such as drink alcohol to the point of getting drunk and do not consistently use condoms when engaging in sex has nothing to do with lack of knowledge, but more to do with peer pressure. Do you think peer pressure is a factor for young junior enlisted Marines?
7. Why do you think young men your age who are not married or in a long-term relationship impregnate women when they do not plan to?
8. Do you think that STDs such as chlamydia and gonorrhea are a problem for young junior enlisted Marines?
9. What do you think are the main reasons why young junior enlisted Marines do not consistently use birth control? Do you think it is different for men and women in the Corps?
10. Are there advantages to being active duty, pregnant (or having a child), and being unmarried? Are there any disadvantages?
11. How knowledgeable do you think other young junior enlisted Marines are about the different types of birth control that are available?
12. How skillful do you think young junior enlisted women Marines are at using birth control? What about men?
13. In general, do you think that drinking alcohol to the point of passing out is a problem for young junior enlisted Marines? Is that a problem in general for men? For women?



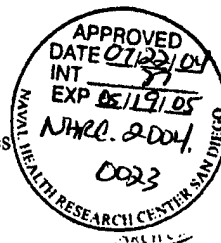
14. Can you describe social situations in which young junior enlisted Marines typically drink? Are there differences in where young women and men in the Corps typically drink?
15. Do you think that sexual violence is a problem for Marines? We are defining sexual violence as unwanted sexual attention, sexual harassment, sexual coercion, or sexual assault.
16. Specifically what do you think is the biggest concern for male Marines? What is the biggest concern for women Marines?
17. What do you think is the best solution for addressing sexual violence in the Corps?

Health Care Services

18. Where do most young junior enlisted Marines typically get health care for STDs? For unintended pregnancies?
19. In the general population, it is well known that women avoid having pelvic examinations, is that also true for Marines? If yes, why? If no, why not?
20. In the general population, it is well known that men avoid being screened for STDs, is that true for Marines? If yes, why? If no, why not?
21. Are there any barriers or problems to using the military health system for health concerns such as STDs? Unintended pregnancies? Alcohol abuse? Sexual violence?
22. Do you think that if a young junior enlisted Marine was diagnosed with an STD would he/she talk to his/her immediate supervisor? Had a problem with alcohol or any of substances? A victim/perpetrator of sexual violence?
23. Have you received information from your command about STDs? Alcohol or other substance use? Sexual violence?

Interventions

24. What specific information should we give young recruits who will participate in our program in terms of preventing STDs? Unintended pregnancies? Alcohol abuse? Sexual violence?
25. What skills should we provide to young recruits who will participate in our program regarding prevention of STDs? Unintended pregnancies? Alcohol abuse? Sexual violence?
26. Should the skills be different for men than for women? If yes, specifically what should the differences be?



*Preventing Health Damaging Behaviors and Negative Health Outcomes in Army and Marine Corps
Personnel During Their First Tour of Duty*

FOCUS GROUP WITH FEMALE JUNIOR ENLISTED MARINES

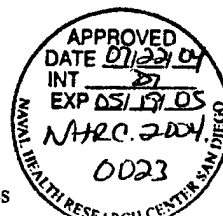
Welcome, and thank you for agreeing to participate in our group discussion. The purpose of this discussion is to learn about the risk and prevention of sexually transmitted infections, unintended pregnancies, alcohol and other substance misuse, and sexual violence in Marines during their first tour of duty.

I am _____ and I am a _____ from the University of California, San Francisco. Also with me today is my colleague _____ also from the University of California, San Francisco. I will let her introduce herself to you. We are collaborating on a research project to determine effective and creative ways of reducing the risk and preventing negative health outcomes in male and female Marines during their first tour of duty.

The reason you were asked to participate in this discussion today is to provide us with first-hand information about what you see as the most important issues which threaten the health and military readiness of young Marines. We are particularly interested in your views and opinions. There are no right or wrong answers, but rather differing points of view. Please feel free to share your point of view even if it differs from what others have said. Also, it is important that you do NOT mention any names of other personnel during these focus group discussions. It is also important that you do NOT tell others outside this room what a specific person said. If you believe you cannot adhere to these two requirements, please inform the focus group facilitator immediately. It is also important not to reveal any personal information as there is no guarantee that what you say will not be repeated outside this room by other participants/ Revealing confidential information could lead to embarrassment and possible disciplinary actions under the Uniform Code of Military Justice.

Before we begin, I would like to make a few points about how we will run this session:

- (1) The information you provide to us will be utilized to develop health promotion interventions for Marine Corps recruits.
- (2) The information you provide in this group is confidential; names will not be used in any summary of this discussion.
- (3) Please keep in mind that we are just as interested in the negative comments as the positive comments, and many times the negative comments are the most helpful.
- (4) Our session today will last about two hours and we will not be taking a formal break.



General Perceptions

1. Why do you think young women choose to join the Marine Corps?
2. After recruit training, what do think are the most stressful things about being a young Marine? (Career/job? Personal life?)
3. Some people think that many young people in the military get married much younger than their same-age peers who are not in the military. Do you share that perception? Why do you think this is (is not) the case?

Risk Factors

4. Can you tell me your perceptions about social situations for Marines after MCT training (during service school)? Do you think the experiences are the same or different for men and women? In what ways are they the same and in what ways are they different?
5. Can you describe the social situations for Marines living in barracks during service school training?
6. Some research indicates that reasons why young people engage in risk behaviors such as drink alcohol to the point of getting drunk and do not consistently use condoms when engaging in sex has nothing to do with lack of knowledge, but more to do with peer pressure. Do you think peer pressure is a factor for young junior enlisted women Marines?
7. Why do you think young men in your age group who are not married or in a long-term relationship impregnate women when they do not plan to?
8. Do you think that STDs such as chlamydia and gonorrhea are a problem for young junior enlisted women Marines?
9. What do you think are the main reasons why young junior enlisted women Marines do not consistently use birth control? Do you think it is different for men and women in the Corps?
10. Are there advantages to being active duty, pregnant (or having a child), and being unmarried? Are there any disadvantages?
11. How knowledgeable do you think other young junior enlisted Marines are about the different types of birth control that are available?
12. How skillful do you think young junior enlisted women Marines are at using birth control? What about men?
13. In general, do you think that drinking alcohol to the point of passing out is a problem for young junior enlisted Marines? Is that a problem in general for men? For women?



14. Can you describe social situations in which young junior enlisted Marines typically drink? Are there differences in where young women and men in the Corps typically drink?
15. Do you think that sexual violence is a problem for Marines? We are defining sexual violence as unwanted sexual attention, sexual harassment, sexual coercion, or sexual assault.
16. Specifically what do you think is the biggest concern for male Marines? What is the biggest concern for women Marines?
17. What do you think is the best solution for addressing sexual violence in the Corps?

Health Care Services

18. Where do most young junior enlisted women Marines typically get health care for STDs? For unintended pregnancies?
19. In the general population, it is well known that women avoid having pelvic examinations, is that also true for Marines? If yes, why? If no, why not?
20. Are there any barriers or problems to using the military health system for health concerns such as STDs? Unintended pregnancies? Alcohol abuse? Sexual violence?
21. Do you think that if a young junior enlisted woman Marine was diagnosed with an STD would she talk to her immediate supervisor? Had a problem with alcohol or any of substances? A victim/perpetrator of sexual violence?
22. Have you received information from your command about STDs? Alcohol or other substance use? Sexual violence?

Interventions

23. What specific information should we give young recruits who will participate in our program in terms of preventing STDs? Unintended pregnancies? Alcohol abuse? Sexual violence?
24. What skills should we provide to young recruits who will participate in our program regarding prevention of STDs? Unintended pregnancies? Alcohol abuse? Sexual violence?
25. Should the skills be different for men than for women? If yes, specifically what should the differences be?



*Preventing Health Damaging Behaviors and Negative Health Outcomes in Army and Marine Corps
Personnel During Their First Tour of Duty*

FOCUS GROUP WITH MALE JUNIOR ENLISTED MARINES

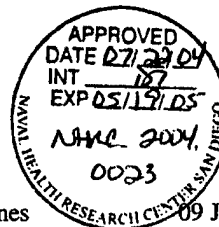
Welcome, and thank you for agreeing to participate in our group discussion. The purpose of this discussion is to learn about the risk and prevention of sexually transmitted infections, unintended pregnancies, alcohol and other substance misuse, and sexual violence in Marines during their first tour of duty.

I am _____ and I am a _____ from the University of California, San Francisco. Also with me today is my colleague _____ also from the University of California, San Francisco. I will let her introduce herself to you. We are collaborating on a research project to determine effective and creative ways of reducing the risk and preventing negative health outcomes in male and female Marines during their first tour of duty.

The reason you were asked to participate in this discussion today is to provide us with first-hand information about what you see as the most important issues which threaten the health and military readiness of young Marines. We are particularly interested in your views and opinions. There are no right or wrong answers, but rather differing points of view. Please feel free to share your point of view even if it differs from what others have said. Also, it is important that you do NOT mention any names of other personnel during these focus group discussions. It is also important that you do NOT tell others outside this room what a specific person said. If you believe you cannot adhere to these two requirements, please inform the focus group facilitator immediately. It is also important not to reveal any personal information as there is no guarantee that what you say will not be repeated outside this room by other participants/ Revealing confidential information could lead to embarrassment and possible disciplinary actions under the Uniform Code of Military Justice.

Before we begin, I would like to make a few points about how we will run this session:

- (1) The information you provide to us will be utilized to develop health promotion interventions for Marine Corps recruits.
- (2) The information you provide in this group is confidential; names will not be used in any summary of this discussion.
- (3) Please keep in mind that we are just as interested in the negative comments as the positive comments, and many times the negative comments are the most helpful.
- (4) Our session today will last about two hours and we will not be taking a formal break.

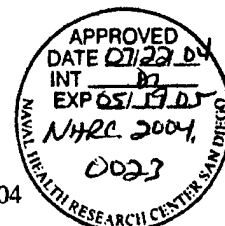


General Perceptions

1. Why do you think young men choose to join the Marine Corps?
2. After recruit training, what do think are the most stressful things about being a young Marine? (Career/job? Personal life?)
3. Some people think that many young people in the military get married much younger than their same-age peers who are not in the military. Do you share that perception? Why do you think this is (is not) the case?

Risk Factors

4. Can you tell me your perceptions about social situations for Marines after MCT training (during service school)? Do you think the experiences are the same or different for men and women? In what ways are they the same and in what ways are they different?
5. Can you describe the social situations for Marines living in barracks during service school training?
6. Some research indicate that reasons why young people engage in risk behaviors such as drink alcohol to the point of getting drunk and do not consistently use condoms when engaging in sex has nothing to do with lack of knowledge, but more to do with peer pressure Do you think peer pressure is a factor for young junior enlisted Marines?
7. Why do you think young men your age who are not married or in a long-term relationship impregnate women when they do not plan to?
8. Do you think that STDs such as chlamydia and gonorrhea are a problem for young junior enlisted Marines?
9. What do you think are the main reasons why young junior enlisted Marines do not consistently use birth control? Do you think it is different for men and women in the Corps?
10. Are there advantages to being active duty, pregnant (or having a child), and being unmarried? Are there any disadvantages?
11. How knowledgeable do you think other young junior enlisted male Marines are about the different types of birth control that are available?
12. How skillful do you think young junior enlisted women Marines are at using birth control? What about men?
13. In general, do you think that drinking alcohol to the point of passing out is a problem for young junior enlisted Marines? Is that a problem in general for men? For women?



14. Can you describe social situations in which young junior enlisted Marines typically drink?
Are there differences in where young women and men in the Corps typically drink?
15. Do you think that sexual violence is a problem for Marines? We are defining sexual violence as unwanted sexual attention, sexual harassment, sexual coercion, or sexual assault.
16. Specifically what do you think is the biggest concern for male Marines? What is the biggest concern for women Marines?
17. What do you think is the best solution for addressing sexual violence in the Corps?

Health Care Services

18. Where do most young junior enlisted Marines typically get health care for STDs? For unintended pregnancies?
19. In the general population, it is well known that men avoid being screened for STDs, is that true for Marines? If yes, why? If no, why not?
20. Are there any barriers or problems to using the military health system for health concerns such as STDs? Unintended pregnancies? Alcohol abuse? Sexual violence?
21. Do you think that if a young junior enlisted male Marine was diagnosed with an STD would he talk to his immediate supervisor? Had a problem with alcohol or any of substances? A victim/perpetrator of sexual violence?
22. Have you received information from your command about STDs? Alcohol or other substance use? Sexual violence?

Interventions

23. What specific information should we give young recruits who will participate in our program in terms of preventing STDs? Unintended pregnancies? Alcohol abuse? Sexual violence?
24. What skills should we provide to young recruits who will participate in our program regarding prevention of STDs? Unintended pregnancies? Alcohol abuse? Sexual violence?
25. Should the skills be different for men than for women? If yes, specifically what should the differences be?



*Preventing Health Damaging Behaviors and Negative Health Outcomes in Army and Marine Corps
Personnel During Their First Tour of Duty*

FOCUS GROUP WITH FEMALE MARINE CORPS RECRUITS

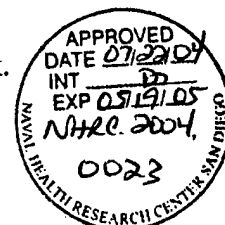
Welcome, and thank you for agreeing to participate in our group discussion. The purpose of this discussion is to learn about the risk and prevention of sexually transmitted infections, unintended pregnancies, alcohol and other substance misuse, and sexual violence in Marines during their first tour of duty.

I am _____ and I am a _____ from the University of California, San Francisco. Also with me today is my colleague _____ also from the University of California, San Francisco. I will let her introduce herself to you. We are collaborating on a research project to determine effective and creative ways of reducing the risk and preventing negative health outcomes in male and female Marines during their first tour of duty; however, we plan to conduct the interventions during recruit training.

The reason you were asked to participate in this discussion today is to provide us with first-hand information about what you see as the most important issues which threaten the health and military readiness of young Marines. We are particularly interested in your views and opinions. There are no right or wrong answers, but rather differing points of view. Please feel free to share your point of view even if it differs from what others have said. Also, it is important that you do NOT mention any names of other personnel during these focus group discussions. It is also important that you do NOT tell others outside this room what a specific person said. If you believe you cannot adhere to these two requirements, please inform the focus group facilitator immediately. It is also important not to reveal any personal information as there is no guarantee that what you say will not be repeated outside this room by other participants/ Revealing confidential information could lead to embarrassment and possible disciplinary actions under the Uniform Code of Military Justice.

Before we begin, I would like to make a few points about how we will run this session:

- (1) The information you provide to us will be utilized to develop health promotion interventions for Marine Corps recruits.
- (2) The information you provide in this group is confidential; names will not be used in any summary of this discussion.
- (3) Please keep in mind that we are just as interested in the negative comments as the positive comments, and many times the negative comments are the most helpful.
- (4) Our session today will last about two hours and we will not be taking a formal break.



Our first question has to do with your reason for joining the Marine Corps.

1. Why do you think young women choose to join the Corps?

The next set of questions has to do with sexually transmitted diseases/STDs/VD.

2. What are some common STDs women get?
3. How can a woman tell if she has an STD?
4. What are some symptoms for STDs? Do women always have symptoms?
5. Can a woman tell if a man has an STD?
6. What are some complications that women may develop after getting an STD?
7. What are some of the biggest challenges women have in trying to protect themselves from getting an STD?
8. What are some of the biggest challenges young women have in trying to prevent an unintended pregnancy?
9. What are some of the reasons why women do not insist that her partner wears a condom?
10. If you were to come up with a description of the type(s) of women who get STDs, what would that be? (Note-- these are only prompts if there are no immediate responses-- is she naïve, one with low self-esteem, ambitious, etc?)
11. What are some of the factors that influence whether a woman will or will not use condoms (or insist that her partner use condoms) to protect herself from STDs?
12. What are some of the factors that influence whether a woman will or will not use birth control methods for preventing unintended pregnancies?
13. How knowledgeable do you think women recruits are about the different types of birth control that are available?
14. How skillful do you think women recruits are at using birth control (getting her partner to use a condom)?
15. Do you think that drinking alcohol to the point of passing out is a problem for young women your age?



16. Some research indicates that reasons why young people engage in risk behaviors such as drink alcohol to the point of getting drunk and do not consistently use condoms when engaging in sex has nothing to do with lack of knowledge, but more to do with peer pressure, do you think this is also true for young men and women in the Corps?
17. Do you think that sexual violence is a problem for young women your age? We are defining sexual violence as unwanted sexual attention, sexual harassment, sexual coercion, or sexual assault.
18. Do you think sexual violence is a problem in the Marine Corps?

The next few questions have to do with seeking health care.

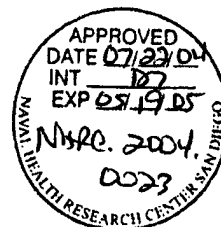
20. What do you think will happen to someone (or a military career) if they were diagnosed with an STD? Became pregnant as an unmarried woman? Had a problem with alcohol or other substances? Was a victim of sexual violence?
21. Do you think that if a young junior enlisted woman Marine was diagnosed with an STD would she talk to her immediate supervisor? Had a problem with alcohol or any of substances? A victim/perpetrator of sexual violence?
22. Have you received information from your command about STDs? Alcohol or other substance use? Sexual violence? Would you like information on these topics?

The following questions have to do with the type of strategies we should use to develop effective programs that will be of interest to women like you.

23. What is the most important message we should convey to all women who will be involved in our programs?
24. What can we say as part of the education program to convince young women that STDs can result in serious health problems that can affect them for years to come?
25. Assuming you have a younger sister, what would you say to her about being safe and staying healthy?
26. Given that STDs and pregnancies are personal issues, how can we get young women such as you to be interested in participating in our program? What would be the main reason for not participating in our program?
27. What can we do to convince each participant that we will not share any of the information that is discussed in our program?



28. The routine way to screen women for STDs requires a pelvic examination, however, in our program we will use urine and self-administered vaginal swabs, the size of a q-tip. Do you think these techniques will be acceptable to young women participating in our program? If yes, why? If no, why not?
29. What specific information should we give women recruits who will participate in our program in terms of preventing STDs? Unintended pregnancies? Alcohol abuse? Sexual violence?
30. What skills should we provide to recruits who will participate in our program regarding prevention of STDs? Unintended pregnancies? Alcohol abuse? Sexual violence?
31. Should the skills be different for women and men? If yes, specifically what should the differences be?
32. Is there any other information that we must be sure to discuss in our program?



*Preventing Health Damaging Behaviors and Negative Health Outcomes in Army and Marine Corps Personnel
During Their First Tour of Duty*

FOCUS GROUP WITH MALE MARINE CORPS RECRUITS

Welcome, and thank you for agreeing to participate in our group discussion. The purpose of this discussion is to learn about the risk and prevention of sexually transmitted infections, unintended pregnancies, alcohol and other substance misuse, and sexual violence in Marines during their first tour of duty.

I am _____ and I am a _____ from the University of California, San Francisco. Also with me today is my colleague _____ also from the University of California, San Francisco. I will let her introduce herself to you. We are collaborating on a research project to determine effective and creative ways of reducing the risk and preventing negative health outcomes in male and female Marines during their first tour of duty; however, we plan to conduct the interventions during recruit training.

The reason you were asked to participate in this discussion today is to provide us with first-hand information about what you see as the most important issues which threaten the health and military readiness of young Marines. We are particularly interested in your views and opinions. There are no right or wrong answers, but rather differing points of view. Please feel free to share your point of view even if it differs from what others have said. Also, it is important that you do NOT mention any names of other personnel during these focus group discussions. It is also important that you do NOT tell others outside this room what a specific person said. If you believe you cannot adhere to these two requirements, please inform the focus group facilitator immediately. It is also important not to reveal any personal information as there is no guarantee that what you say will not be repeated outside this room by other participants/ Revealing confidential information could lead to embarrassment and possible disciplinary actions under the Uniform Code of Military Justice.

Before we begin, I would like to make a few points about how we will run this session:

- (1) The information you provide to us will be utilized to develop health promotion interventions for Marine Corps recruits.
- (2) The information you provide in this group is confidential; names will not be used in any summary of this discussion.
- (3) Please keep in mind that we are just as interested in the negative comments as the positive comments, and many times the negative comments are the most helpful.
- (4) Our session today will last about two hours and we will not be taking a formal break.

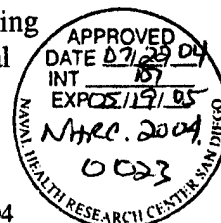


Our first question has to do with your reason for joining the Marine Corps.

1. Why do you think that young men choose to join the Corps?

The next set of questions has to do with sexually transmitted diseases/STDs/VD.

2. What are some common STDs men get?
3. What are some symptoms of STDs?
4. Do men always have symptoms?
4. Can a man tell if a woman has an STD?
5. What are some complications that men may develop after getting an STD?
6. What are some of the biggest challenges men have in trying to protect themselves from getting an STD?
7. What are some of the biggest challenges young men have in trying to prevent an unintended pregnancy?
8. If you were to come up with a description of the type(s) of men who get STDs, what would that be? (Note-- these are only prompts if there are no immediate responses-- is she naïve, one with low self-esteem, ambitious, etc?)
9. What are some of the factors that influence whether a man will or will not use condoms to protect himself from STDs?
10. Should men play an active role in helping his partner choose birth control to prevent unintended pregnancies?
11. How knowledgeable do you think male recruits are about the different types of birth control that are available?
12. Do you think that drinking to the point of passing out is that a problem for young men your age?
13. Some research indicates that reasons why young people engage in risk behaviors such as drink alcohol to the point of getting drunk and do not consistently use condoms when engaging in sex has nothing to do with lack of knowledge, but more to do with peer pressure, do you think this is also true for young men and women in the Corps?
14. Do you think that sexual violence is a problem for your young men your age? We are defining sexual violence as unwanted sexual attention, sexual harassment, sexual coercion, or sexual assault.



15. Do you think sexual violence is a problem in the Marine Corps?

The next few of questions have to do with seeking health care.

17. What do you think will happen to someone (or a military career) if they were diagnosed with an STD? Impregnated a woman as an unmarried man? Had a problem with alcohol or other substances? Was a victim/perpetrator of sexual violence?

18. Do you think that if a young junior enlisted male Marine was diagnosed with an STD would he talk to his immediate supervisor? Had a problem with alcohol or any of substances? A victim/perpetrator of sexual violence?

19. Have you received information from your command about STDs? Alcohol or other substance use? Sexual violence? Would you like to have information on these issues?

The following questions have to do with the type of strategies we should use to develop effective programs that will be of interest to women like you?

20. What is the most important message we should convey to all men who will be involved in our programs?

21. What can we say as part of the education program to convince young men that STDs can result in serious health problems that can affect them for years to come?

22. Assuming you have a younger brother, what would you say to him about being safe and staying healthy?

23. Given that STDs and pregnancies are personal issues, how can we get young men such as you to be interested in participating in our program? What would be the main reason for not participating in our program?

24. What can we do to convince each participant that we will not share any of the information that is discussed in our program?

25. In the general population, it is well known that men avoid being screened for STDs, is that also true for recruits such as you? If yes, why? If no, why not?

26. What specific information should recruits who will participate in our program in terms of preventing STDs? Unintended pregnancies? Alcohol abuse? Sexual violence?

27. What skills should we provide to recruits who will participate in our program regarding prevention of STDs? Unintended pregnancies? Alcohol abuse? Sexual violence?



28. Should the skills be different for women and men? If yes, specifically what should the differences be?

29. Is there any other information that we must be sure to discuss in our program?



Attachment 8.

Investigators' IRB Training Certificates



Human Subject Protections: Basic Course

Completion Certificate

This is to certify that

Cherrie Boyer

has completed the **UCSF Human Subject Protections: Basic Course** online course, developed by the University of California, San Francisco (UCSF), on 04/17/2003.

This course included the following:

- Key historical events and current issues that impact guidelines and legislation on human participant protection in research.
 - Ethical principles and guidelines that should assist in resolving the ethical issues inherent in the conduct of research with human participants.
 - The use of key ethical principles and federal regulations to protect human participants at various stages in the research process.
 - A description of guidelines for the protection of special populations in research.
 - A definition of informed consent and components necessary for a valid consent.
 - A description of the role of the IRB in the research process.
 - The roles, responsibilities, and interactions of federal agencies, institutions, and researchers in conducting research with human participants.
-



Human Subject Protections: Basic Course

Completion Certificate

This is to certify that

Mary-Ann Shafer

has completed the **UCSF Human Subject Protections: Basic Course** online course, developed by the University of California, San Francisco (UCSF), on 05/22/2003.

This course included the following:

- Key historical events and current issues that impact guidelines and legislation on human participant protection in research.
 - Ethical principles and guidelines that should assist in resolving the ethical issues inherent in the conduct of research with human participants.
 - The use of key ethical principles and federal regulations to protect human participants at various stages in the research process.
 - A description of guidelines for the protection of special populations in research.
 - A definition of informed consent and components necessary for a valid consent.
 - A description of the role of the IRB in the research process.
 - The roles, responsibilities, and interactions of federal agencies, institutions, and researchers in conducting research with human participants.
-



Human Subject Protections: Basic Course

Completion Certificate

This is to certify that

Julius Schachter

has completed the UCSF Human Subject Protections: Basic Course online course, developed by the University of California, San Francisco (UCSF), on 10/03/2003.

This course included the following:

- Key historical events and current issues that impact guidelines and legislation on human participant protection in research.
 - Ethical principles and guidelines that should assist in resolving the ethical issues inherent in the conduct of research with human participants.
 - The use of key ethical principles and federal regulations to protect human participants at various stages in the research process.
 - A definition of informed consent and components necessary for a valid consent.
 - A description of the role of the IRB in the research process.
 - The roles, responsibilities, and interactions of federal agencies, institutions, and researchers
-

**U.S. Army Research Institute
of Environmental Medicine**

CERTIFICATE OF COMPLETION

**UNIVERSITY OF MIAMI
COLLABORATIVE IRB TRAINING
INITIATIVE**

**CORE COURSE IN THE
PROTECTION OF HUMAN
RESEARCH SUBJECTS**

CPT LOLITA BURRELL, Ph.D.

**Virginia Thompson_01Apr 04
USARIEM SITE ADMINISTRATOR**

CITI Course in The Protection of Human Research Subjects**Thursday, June 3, 2004****CITI Course Completion Record
for Caron Wilbur**

To whom it may concern:

On 6/3/2004, *Caron Wilbur* (username=caronwilbur) completed all *CITI Program* requirements for the *Basic CITI Course in The Protection of Human Research Subjects*.

Learner Institution: *Brooke Army Medical Center***Learner Group:** *Group 3.***Learner Group Description:** *This group will complete instructional materials appropriate for investigators and staff conducting **Social & Behavioral Research**.***Contact Information:**

Department: Department of Combat Medic Training

Role in human subjects research: OTHER

Mailing Address:

1203 Calcutta Lane

San Antonio

TX

78258

Email: caron.wilbur@cen.amedd.army.mil

Office Phone: 210-221-3118

	Date completed
The Required Modules for Group 3. are:	
Introduction	06/02/04
History and Ethical Principles - SBR	06/02/04
The Regulations and The Social and Behavioral Sciences - SBR	06/02/04
Assessing Risk in Social and Behavioral Sciences - SBR	06/03/04
Informed Consent - SBR	06/03/04
HIPAA and Human Subjects Research	06/03/04
Brooke Army Medical Center	06/03/04

Additional optional modules completed:	Date completed
---	-----------------------

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiler Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

Attachment 9.

Commanding Officers' Letters of Support



DEPARTMENT OF THE ARMY
32D MEDICAL BRIGADE, U.S. ARMY MEDICAL DEPARTMENT CENTER AND SCHOOL
2355 HARNEY ROAD, SUITE 93
FORT SAM HOUSTON, TEXAS 78234-5093

REPLY TO
ATTENTION OF

May 3, 2004

Office of the Brigade Commander

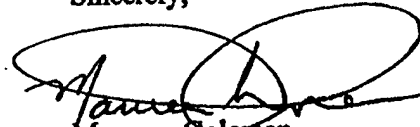
Cherrie B. Boyer, Ph.D.
Division of Adolescent Medicine
University of California, San Francisco
3333 California Street, Suite 245
Box 0503
San Francisco, California 94143-0503

Dear Dr. Boyer:

This letter is to indicate my full support for your study entitled, "Preventing Health Damaging Behaviors in Army and Marine Corps Recruits". I understand that at the 32d Medical Brigade, Fort Sam Houston, this study will proceed through two phases: the initial focus group discussion phase, and the actual implementation of a behavioral intervention to prevent sexually transmitted infections, unintended pregnancies, alcohol misuse, and sexual violence among soldiers, with collection of biological specimens to screen for sexually transmitted infections. I understand that although you will have a staff in place to implement all aspects of the study, my staff will work with you and your research team to work out the logistics of this very important study.

For further information, I may be reached at (210) 221-5105.

Sincerely,


Maureen Coleman
Colonel, U.S. Army
Brigade Commander



UNITED STATES MARINE CORPS

MARINE CORPS RECRUIT DEPOT/EASTERN RECRUITING REGION
PO BOX 19001
PARRIS ISLAND, SOUTH CAROLINA 29905-9001

4 May 2004

Cherrie B. Boyer, PhD
Professor
Department of Pediatrics
Division of Adolescent Medicine
University of California, San Francisco
3333 California Street, Suite 245
Box 0503
San Francisco, CA 94143-0503

Dear Dr. Boyer:

This letter is to indicate Marine Corps Recruit Depot Parris Island full support for your study entitled, "Preventing Health Damaging Behaviors in Marine Corps Recruits. MCRD's understanding is that this study will proceed in two phases, which include the initial focus group discussion phase, and the actual implementation phase. We understand the actual implementation phase consist of a behavioral intervention to prevent sexually transmitted infections, unintended pregnancies, alcohol misuse, and sexual violence among Marine Corps recruits, with collection of biological specimens to screen for sexually transmitted infections. MCRDPI understands that although you will have a staff in place to implement all aspects of the study, they will coordinate with the Depot staff and your research team to work out the logistics of this very important study.

Sincerely,

G. A. Biszak
Colonel, United States Marine Corps



DEPARTMENT OF THE NAVY

NAVAL HOSPITAL
1 PINCKNEY BOULEVARD
BEAUFORT, SOUTH CAROLINA 29902-6148

IN REPLY REFER TO:

6500
Ser 00/04085
18 MAY 2004

Cherrie B. Boyer, PhD
Professor, Department of Pediatrics
Division of Adolescent Medicine
University of California, San Francisco
3333 California Street, Suite 245
Box 0503
San Francisco, CA 94143-0503

Reference: COL Biszak's letter of 4 May 2004

Dear Dr. Boyer:

This letter is to document Naval Hospital Beaufort's support for your study entitled, "Preventing Health Damaging Behaviors in Army and Marine Corps Recruits". I am aware that the study will take place at the Marine Corps Recruiting Depot, Parris Island, SC, with the support of the Commanding General and will proceed through two phases: The initial focus group discussion phase and the actual implementation of a behavioral intervention to prevent sexually transmitted infections, unintended pregnancies, alcohol misuse, and sexual violence among Marine Corps recruits. Also, there will be a collection of biological specimens to screen for sexually transmitted infections.

I understand that you will have a staff in place to implement all aspects of the study and will work with the MCRD staff to work out the logistics of this study.

Sincerely,

A handwritten signature in black ink, appearing to read "J. R. Hoffower", is positioned above the typed name.

J. R. HOFFOWER
Captain, Nurse Corps
United States Navy
Commanding Officer

Modification

- f. **HRPP #:** NHRC.2002.0018 (previously #32269)
Title: Influence of Individual Difference and Task Difficulty on Cerebral and Behavioral Responses During Cognitive Performance Following Total Sleep Deprivation
PI: Walter Car, LT, MSC, USNR
WU#: Neuroimaging Sleep Debt, 60216

The Principal Investigator submitted a modification application for a protocol that was previously classified as greater than minimal risk. This study seeks to examine cognitive performance and cerebral activation differences in two groups who show a differential need for sleep: habitual long-sleepers and habitual short-sleepers. The modification submission requested: 1) permission to contact 13 previous participants to re-run those subjects now that a new functional magnetic resonance imaging (fMRI) scanning machine has been procured, and 2) addition of a new cognitive test in the fMRI portion of the data collection protocol.

With a vote of 6 for, 0 against, Chair abstaining, and no members disqualified from the review, the Board recommended to approve the indicated modifications of this greater than minimal risk protocol after the following issues are addressed:

1. Global—On all documents, change protocol number to "NHRC.2002.0018".
2. Protocol:
 - a. General—Remove bolding from changes that were previously approved (i.e., March 2004 changes) and remove reference to Dr. Gillin on page 4.
 - b. Page iii, Section III, Record of Changes, #4—Insert "2004" after "CHANGES SUBMITTED 11 MAY".
 - c. Page 4, Initial Screening—Provide copy of the letter to be sent to former subjects for IRB review and approval prior to use in the study. In addition, clarify whether previous subjects will be "re-screened" (i.e., undergo actigraphy screening period, undergo complete testing, etc.)
3. Provide VAMC and UCSD IRB approval of modification, when available.

3. New Business

Initial Submissions

- a. **HRPP #:** NHRC.2004.0023
Title: Preventing Health Damaging Behaviors in Army and Marine Corps Recruits
Abbrev Title: Preventing Health Damaging Behaviors
PI: Cherrie B. Boyer, PhD
WU#: N/A

The Principal Investigator submitted this protocol for initial review. The study is being conducted by investigators from the University of California, San Francisco (UCSF), and the United States Army Research Institute of Environmental Medicine. It is part of a multi-phased study to prevent sexually transmitted infections, unintended pregnancies, alcohol and other substance misuse, and exposure to or involvement with sexual violence in Marine Corps recruits and Army advance individual trainees. This elicitation (focus group) phase of the study will collect information from focus groups involving 168 male and female active duty subjects to be used for the development of the interventions and pre- and post-intervention evaluation questionnaires. Subjects will be recruited from the Fort Sam Houston Medical Brigade and the Marine Corps Recruiting Depot, Parris Island, South Carolina. IRB approval was received from UCSF and is pending from Brooke Army Medical Center. NHRC IRB is reviewing this proposal as this study involves Naval personnel, and is only concerning itself with the Marine Corps subjects portion of this study.

The extent of NHRC's approval authority over the external institution's (UCSF's) conduct of this study was discussed. NHRC IRB review of this protocol is to serve the protection of human subjects in the Marine Corps participant's portions of this study, and is not an endorsement of the study. Investigators will be advised on NHRC's reporting requirements regarding adverse events, modifications, continuing reviews and final reports.

With a vote of 6 for, 0 against, Chair abstaining, and no members disqualified from the review, the Board classified this protocol as minimal risk. On a vote of 6 for, 0 against, Chair abstaining, and no members disqualified from the review, the Board recommended to approve this minimal risk protocol for a period of one year after the below-stated issues are addressed. The IRB Chair and IRB medical representative will review the revised focus group questions, informed consent document and recruitment script. Needed administrative changes are also noted below.

1. This protocol has been assigned protocol number "NHRC.2004.0023". Please update "Protocol #" to read "Protocol #NHRC.2004.0023 throughout protocol accordingly.
2. Please provide original signature for Dr. Boyer on investigator assurance agreement. Stamped signatures are not acceptable.
3. Page 4, Section VI(1)(A) Subjects—Describe how "age" will be confirmed. The Board recommends that a statement be added to the informed consent document whereby the subject confirms his/her age. e.g., revise last sentence to read: "If you agree to participate and **are at least 18 years of age or older** you should sign below. Age requirement should also be included in the recruitment script.
4. Page 4, Section VI(1)(B) (para. 2, line 3-4) Recruiting non-training—Change to "No military personnel other than potential participants" will be present during ...
5. Recruitment (General Comment)—It is noted that Marine Corps recruits may not be permitted to have pizza and soda during training. Please ensure this is allowed by involved commands, or revise, if necessary.
6. Page 4, Section VI(1)(B) Methods, Consent Process—Section describes informed consent and then states that subjects will be given the Human Subjects Bill of Rights Statement. The Bill must be presented prior to initiating the consent process specific to the study; therefore, move the sentence referring to the Bill to precede the informed consent process. Assumedly, this is the "California Experimental Subject's Bill of Rights" being referenced. The NHRC IRB does not mandate use of this form for this study.
7. Page 5 – Duties and Responsibilities—Define Dr. Rick Shaffer's role and responsibilities. He is not Program Manager, as his signature on page ii would imply.
8. Page 6, Section VIII(1) Safeguards for Protecting Subjects:
 - a. Section states that investigators will report participants who show signs of or report psychological discomfort to his/her drill instructor/class instructor for care. This is NOT allowed by this IRB. Participants should be told to notify their instructor and or health care provider, if needed. [This procedures is also listed in Section VIII(3) and should be deleted.]
 - b. Section VIII(1) Safeguards—Provide names of any facilitators not listed as investigators. Use of text denoting a "designated focus group facilitator" is not acceptable.
 - c. Section VIII(1) Safeguards—Indicate here that all participants will be instructed not to name specific individuals in their discussions.
9. Page 7, Section IX(1) Experimental Data:
 - a. Describe how rank of subjects will be known/determined.
 - b. Briefly describe plan for data analysis.
10. Appendix B-1, Investigator Assurance Agreement (IAA)—For IAAs signed by Drs. Shafer and Schachter, remove shading (grey highlighting) and brackets on IAA that signed, insert the Protocol Title and header information on this form, have the doctors resign, and forward originals to IRB.
11. Appendix E, References—Provide references for text citations number 25-31.
12. Recruitment flyer – Spell out STDs. Change to "These are issues that may confront young adults."

13. Recruitment script—Add “Sensitive topics will be discussed and may make some people feel uncomfortable.” It is important that you do NOT mention names of any other personnel during these focus group discussions. It is also important not to reveal any personal information, as there is no guarantee that what you say will not be repeated outside this room by other participants. Revealing confidential information could lead to embarrassment and possible disciplinary actions under the Uniform Code of Military Justice.”
14. Attachment 5, Informed Consent Forms (consents for all participants only, unless otherwise noted)
 - a. Page 1, Section A—Spell out abbreviations (STIs, UIPs). (MC Recruits’ Consent Form only.)
 - b. Page 1, Section B(1)—Add statement indicating the total overall number of participants for the study.
 - c. Page 1, Section B(2)—Add in BOLD at bottom of paragraph “It is important that you do NOT mention any names of other personnel during these focus group discussions. It is also important that you do NOT tell others outside this room what a specific person said. If you believe you cannot adhere to these two requirements, please inform the focus group facilitator immediately. It is also important not to reveal any personal information as there is no guarantee that what you say will not be repeated outside this room by other participants. Revealing confidential information could lead to embarrassment and possible disciplinary actions under the Uniform Code of Military Justice
 - d. Page 2, Section B(5)—MC recruits - Delete second sentence; it is confusing and appears to refer to personal identifiers. Correct the numbering of this section. (MC Recruits’ Consent Form only.)
 - e. Page 2, Section B(6)—Sentence is incomplete. Please revise. (MC Junior Enlisted Consent Form only).
 - f. Page 3, Section G – Add at end of paragraph (MC only): Alternatively, if you have questions about your rights as a research participant you may contact Christopher Blood, JD, MA of the Naval Health Research Center at (619) 553-8386 or blood@nhrc.navy.mil.
 - g. Page 3, Section H—Revise first sentence to read “You have received a copy of the “Human Subjects Bill of Rights” (if you are still giving it to them) and will also be given a copy of this consent form and a privacy act statement to keep.”
 - h. Provide a clean copy of ICDs for IRB date stamping.
15. Attachment 7, Focus Group Questionnaires— Many issues came up during review of these documents. Some questions would represent UCMJ violations depending on how they were answered; other questions are personalized and do not represent the types of questions that will shed light on beliefs of the group. These questions must be justified, revised, or removed.
16. Obtaining a ‘Certificate of Confidentiality’ from DHHS should be considered to further protect the confidentiality of the data.
17. Provide a copy of the Brooke’s IRB approval upon receipt.

b. **HRPP #:** **NHRC.2004.0024**
 Title: **Evaluation of the Navy Ship Shape Weight Management Program**
 Abbrev Title: Ship Shape Evaluation
 PI: Linda K. Hervig, M.S.
 WU#: Evaluation of Navy Weight Management Programs, Army Reimbursable-60405

The Principal Investigator submitted this protocol for initial review. This study will assess the impact of the Ship Shape Weight Management program immediately following participation and at 3 and 6-month follow-up periods. Participation in a Navy-approved weight management program is required by the Navy Health and Physical Readiness Program instruction for service members who do not meet the weight-for-height standards. Ninety-five active duty military service members will be recruited for the longitudinal study. Changes in life-style behaviors, body composition, and performance on the physical readiness test (PRT) will be assessed at the beginning and end of the Ship Shape program, and at a 3- and 6-month follow-up.

CHR APPROVAL LETTER

TO: Cherrie Boyer, Ph.D.
Box 0503

Mary-Ann Shafer, M.D.
Box 0503,

RE: Preventing Health Damaging Behaviors and Negative Health Outcomes in Army and Marine Corps Personnel During their First Tour of Duty

The Committee on Human Research (CHR) has reviewed and approved this application to involve humans as research subjects. This included a review of all documents attached to the original copy of this letter.

The CHR is the Institutional Review Board (IRB) for UCSF and its affiliates. UCSF holds Office of Human Research Protections Federalwide Assurance number FWA00000068. See the CHR website for a list of other applicable FWA's.

COMMENT: The approval of this modification is for marine corps subjects only.

APPROVAL NUMBER: H7183-24127-01A. This number is a UCSF CHR number and should be used on all correspondence, consent forms and patient charts as appropriate.

APPROVAL DATE: October 6, 2004


EXPIRATION DATE: January 28, 2005

Expedited Review

GENERAL CONDITIONS OF APPROVAL: Please refer to www.research.ucsf.edu/hr/Apply/hrApprovalCond.asp for a description of the general conditions of CHR approval. In particular, the study must be renewed by the expiration date if work is to continue. Also, prior CHR approval is required before implementing any changes in the consent documents or any changes in the protocol unless those changes are required urgently for the safety of the subjects.

HIPAA "Privacy Rule" (45CFR164): This study does not involve access to, or creation or disclosure of Protected Health Information (PHI).

Sincerely,


Victor I. Reus, M.D.
Chair, Committee on Human Research

cc: Susan Pierce, Box 0503

CHR APPROVAL LETTER

TO: Cherrie Boyer, Ph.D.
Box 0503

Mary-Ann Shafer, M.D.
Box 0503,

RE: Preventing Health Damaging Behaviors and Negative Health Outcomes in Army and Marine Corps Personnel During their First Tour of Duty

The Committee on Human Research (CHR) has reviewed and approved this application to involve humans as research subjects. This included a review of all documents attached to the original copy of this letter.

Specifically, the review included but was not limited to the following documents:
Army Consent Form, Dated 9/25/04

The CHR is the Institutional Review Board (IRB) for UCSF and its affiliates. UCSF holds Office of Human Research Protections Federalwide Assurance number FWA00000068. See the CHR website for a list of other applicable FWA's.

APPROVAL NUMBER: H7183-24127-01B. This number is a UCSF CHR number and should be used on all correspondence, consent forms and patient charts as appropriate.

APPROVAL DATE: November 3, 2004

EXPIRATION DATE: January 28, 2005

Expedited Review

GENERAL CONDITIONS OF APPROVAL: Please refer to www.research.ucsf.edu/hr/Apply/chrApprovalCond.asp for a description of the general conditions of CHR approval. In particular, the study must be renewed by the expiration date if work is to continue. Also, prior CHR approval is required before implementing any changes in the consent documents or any changes in the protocol unless those changes are required urgently for the safety of the subjects.

HIPAA "Privacy Rule" (45CFR164): This study does not involve access to, or creation or disclosure of Protected Health Information (PHI).

Sincerely,



Victor I. Reus, M.D.
Chair, Committee on Human Research

cc: Susan Pierce, Box 0503

HIV/STI Prevention Programs - Summary Chart

Sources:

PsyInfo database
 CDC Effective Programs List <http://www.cdc.gov/hiv/projects/rep/> (Updated March 2004)
 Compendium of HIV Prevention Interventions with Evidence of Effectiveness (CDC 2001)
 Advocates for Youth: "Science and Success: Sex Education and Other Programs That Work to Prevent Teen Pregnancy, HIV and Sexually Transmitted Infections." 2003
 Sociometrics - Program Archive on Sexuality, Health and Adolescence. <http://www.socio.com/pasha.htm>
 "Emerging Answers: Research Findings On Programs to Prevent Teen Pregnancy." National Campaign To Prevent Teen Pregnancy. 2001
 "Making the List: Understanding, Selecting and Replicating Effective Teen Pregnancy Prevention Programs." National Campaign to Prevent Teen Pregnancy. 2004

Program	Target population	Program Content	Evaluation	Program Materials
Becoming a Responsible Teen St. Lawrence JS, Brasfield TL, Jefferson KW <i>et al.</i> Cognitive-behavioral intervention to reduce African American adolescents' risk for HIV infection. <i>Journal of Consulting and Clinical Psychology</i> 1995; 63:221-237. Contact: Janet St. Lawrence, PhD Centers for Disease Control & Prevention (404) 639-8298 nzs4@cdc.gov	African American youth ages 14-18	HIV prevention program based on social learning theory and IMB risk-reduction model. 8 weekly educational and behavior skills sessions; 90-120 min each. Session 1: Local HIV/AIDS demographics, HIV transmission and prevention information, including sexual activity risk continuum. Session 2: Group discussion about sexual decisions, values and pressures, followed by a video for African American youth and video discussion. Session 3: Technical competency skills. Discussion of statewide adolescent sexual activity levels, condom use demonstrations, small group practice, discussion of barriers to condom use, cognitive restructuring of unhelpful beliefs about self-protection and condom use. Session 4-6: Communication skills and assertiveness were taught in 3 contexts: a) initiating discussion about condoms in advance with a sex partner, b) refusing pressure to engage in unprotected sex, and c) sharing HIV-risk information with peers. Leaders demonstrated these skills, followed by participant role play. Session 7: Cognitive competency skills. Local HIV-positive youths discussed how HIV had affected their lives. Discussion of behavioral self-management and problem-solving strategies. Session 8: Social support and empowerment. Participants shared what each felt was most helpful in the program and the personal changes each had made as a result. The impact the group could have by educating friends and families was emphasized, as well as the importance of supportive friendship networks.	Randomized controlled trial Control condition: 1-session HIV education program Pretest and follow-up assessment at 2, 6 and 12 months 246 African American youth; mean age 15.3 Intervention was conducted in a comprehensive health center serving low-income minority clients in a small Mississippi city. Two facilitators, a male and a female, led the sessions. <u>12-month results:</u> Delayed sexual debut Males: decreased incidence of unprotected vaginal, anal and oral sex Females: decreased incidence of unprotected vaginal sex; discontinued unprotected anal sex; increased condom use.	\$49.95 for teachers' manual ETR Associates

AIDS Prevention for Adolescents in School	Target Population	Program	Evaluation	Materials
<p>Walter HJ, Vaughan RD. AIDS risk reduction among a multiethnic sample of urban high school students. <i>JAMA</i> 1993; 270:725-730.</p>	<p>High school students</p> <p>Urban youth</p> <p>Multietnic populations</p>	<p>Program School-based, teacher-delivered HIV prevention curriculum. Six 1-hour lessons.</p> <p>Based on the health belief model, social cognitive theory and a model of social influence. The curriculum emphasizes delaying the initiation of sex and consistent condom use.</p> <p>Program uses role-play and other experiential activities.</p> <p>Lessons 1 & 2: Information about HIV transmission and prevention, including 1) teaching students to accurately appraise their risk of HIV infection, 2) fostering appropriate concern about HIV infection based on youths' individual risk behaviors, and 3) HIV prevention resources within the school and community</p> <p>Lessons 3 & 4: 1) Correcting students' misperceptions regarding their peers' HIV risk behaviors, 2) helping students clarify their individual values, and 3) fostering development of negotiation skills, via role play, to delay sexual debut.</p> <p>Lessons 5 & 6: Condom use negotiation skills, and the knowledge and skills to obtain and correctly use condoms</p>	<p>Quasi-experimental evaluation design, including treatment and comparison conditions, in 4 New York high schools.</p> <p>Pretest and follow-up survey 3 months post-intervention</p> <p>Urban youth (n=1,201 at baseline; n=867 at follow-up); mean age 15.7</p> <p><u>Results:</u></p> <p>Improved knowledge regarding HIV transmission</p> <p>Improvement in attitudes related to risk reduction and self-efficacy</p> <p>Positive change in participants' beliefs about their susceptibility to HIV, attitudes about the benefits of using condoms, and condom use self-efficacy</p> <p>A greater percentage of intervention participants than comparison youth reported behaviors, from baseline to follow-up, that included initiating or continuing monogamy (~23% and 16%, respectively).</p> <p>Reduced number of high-risk sexual partners</p> <p>More consistent condom use between baseline and follow-up.</p> <p>No significant impact on sexual debut.</p>	<p>\$200 for 1 PASHA user's guide; 1 AIDS Prevention for Adolescents in School Curriculum Handbook; Student Activity Book; Video clip; 1 Resource Guide for Sex Educators; 1 set of evaluation instruments; 1 Prevention minimum evaluation data set; other materials.</p> <p>May cost less for manual only.</p>

AIDS Prevention and Health Promotion among Women	Target Population	Program	Evaluation	Materials
<p>Hobfoll SE, Jackson AP, Lavin J. Reducing Inner-City Women's AIDS Risk Activities: A Study of Single, Pregnant Women. <i>Health Psychology</i>. 1994;13(5):397-403.</p>	<p>Although the evaluation study was conducted with pregnant women, the program is appropriate for older adolescent and young adult women (ages 16+).</p> <p>Can be implemented in clinics and community-based organizations.</p>	<p>Program HIV prevention program, aimed at helping participants develop and follow a sexual health action plan.</p> <p>Four 1 1/2- to 2-hour small (2-8 participant) group sessions, conducted over the course of 3 months.</p> <p>Based on concepts of empowerment, group social support and culturally sensitive skill building.</p> <p>Video segments promote group discussion and provide the basis for group role plays. Actors are from a similar population as the target group, and the segments portray a group HIV intervention similar to that experienced by the participants. Video segments demonstrate examples of assertiveness, negotiation skills, planning skills and specialized skills such as cleaning drug works. Tapes also have general interest segments (e.g., healthy sexual positions during later pregnancy.)</p> <p>Main program theme: to help participants develop and apply a health action plan. To support the implementation of these action plans, sessions encouraged a sense of mastery, positive expectation of success, negotiation skills, assertiveness skills, and fear of negative health consequences. Mastery was addressed by reinforcing prior successes and positive actions of participants. Role play included feedback and group discussion of behavioral options.</p> <p>Cognitive rehearsal techniques were used for behaviors such as condom use (i.e., participants imagine themselves problem-solving in the context of a given scenario). Sessions also included aversive conditioning, whereby participants imagine practicing an unhealthy behavior that leads to an aversive outcome. This was paired with a scenario of a healthy behavior leading to a positive outcome. The final session addressed relapse prevention and potential obstacles to healthy behavior.</p>	<p>Random assignment of participants to intervention, a general health promotion control group, or a no-treatment control group. Pretest, immediate post-test, and 6 month post-test.</p> <p>206 low-income African American (57%) and white (40%) women ages 16-29, in second trimester of pregnancy, who were using medical center obstetrics services in Akron, Ohio.</p> <p>Program implemented by female psychologists and health educators.</p> <p>Results: Compared to control groups, both African American and white intervention participants had statistically significant, moderate increases in HIV/AIDS knowledge, safer sex goals and safer-sex behaviors at 6-month follow-up, including spermicide and condom purchase and use.</p> <p>No program effect on abstinence or number of sexual partners.</p>	<p>For \$175:</p> <p>1 PASHA User's Guide</p> <p>1 AIDS Prevention and Health Promotion among Women Program Manual</p> <p>1 Session 1: Drug Use, Alcohol Use and AIDS videotape</p> <p>1 Session 2: Condom and Spermicide Use and Controlling the Conditions of Sexual Encounters videotape</p> <p>1 Session 3: Sexual History, Saying No to an Unwanted Intensive Sexual proposition, Developing a Mutual Sexual Behavior Plan videotape</p> <p>1 Session 4: Relapse Prevention, Post-Intervention Sexual Life, Alternatives to Intercourse, Mutual Monogamy, and Cleaning Drug Works videotape</p> <p>1 Set of Original Evaluation Instruments</p> <p>1 Prevention Minimum Evaluation Data Set (PMEDS)</p>

<p>Get Real About AIDS</p> <p>Main DS, Iverson DC, McGloin J <i>et al.</i> Preventing HIV infection among adolescents: evaluation of a school-based education program. <i>Preventive Medicine</i> 1994; 23:409-417.</p> <p>Contact: Deborah Main, PhD Univ. of Colorado Health Sciences Center (303) 315-9700 debbi.main@uchsc.edu</p>	<p>Target Population</p> <p>Urban, suburban, and rural, multiethnic high school students</p>	<p>Program</p> <p>Skills-based, high school HIV prevention curriculum, based on social cognitive theory and the theory of reasoned action.</p> <p>15 sessions, delivered on consecutive days</p> <p>Utilizes interactive activities, discussion, role-play, simulation and videos. Most lessons focus on skills for use in HIV risk situations.</p> <p>Main program goal: to reduce sexual risk behaviors by delaying the initiation of sex. The program goal for youth who choose to have sex is to encourage abstinence from drug use, consistent and correct condom use, monogamy, and HIV testing.</p> <p>1 session: Teen vulnerability to HIV 2 sessions: Normative determinants of risky behavior 1 session: Condom use 8 sessions: Skills to help participants identify, manage, avoid and exit risky situations</p> <p>The intervention is reinforced through teachers' activities such as displaying posters and distribution of wallet cards with HIV information.</p>	<p>Evaluation</p> <p>Quasi-experimental design, with treatment and comparison conditions, in 17 schools in Colorado. Pretest, and two- and six-month post-tests.</p> <p>The evaluated intervention was based "in part" on the Get Real About AIDS curriculum. Comparison conditions included no education; general health education; or minimal exposure to sexuality education materials.</p> <p>Rural, urban, and suburban youth (n=2,015 at baseline; n=1,477 at six-month follow-up); mean age 15 yrs. 65% white, 21% Hispanic, 6% black.</p> <p>6-month results: Among sexually active students: fewer sexual partners; increased condom purchases and use; greater intentions to engage in sex less often and to use condoms.</p> <p>No effect of intervention on timing of sexual initiation, frequency of sex, or use of alcohol/other drugs.</p>	<p>Materials</p> <p>Material kit for grades 9-12: \$495. The kit includes: teacher's guide, ground rules poster, question box, 7 myth/fact posters, 2 steps posters, a message poster, 4 videos, a resource book, a pamphlet (30 copies), 30 transition cards, and 30 community resource cards. A demo kit includes samples of the myth/fact posters, step posters, videos, and community resource cards. Previews are sent at no charge.</p> <p>AGC Educational Media 1-800-323-9084 agcmedia@starnetinc.com</p>
<p>Be Proud! Be Responsible!</p> <p>Jemmott JB, Jemmott LS, Fong GT. Reductions in HIV risk-associated sexual behaviors among black male adolescents: effects of an AIDS prevention intervention. <i>American Journal of Public Health</i> 1992; 82:372-377</p> <p>Contact: John Jemmott III, PhD U. of Pennsylvania 215-573-9366 jjemmott@asc.upenn.edu</p>	<p>Target Population</p> <p>Black male youth Urban 13- to 18-year-old youth</p>	<p>Program</p> <p>HIV prevention program based on social cognitive theory, the theory of reasoned action, and the theory of planned behavior.</p> <p>Aims to prevent HIV by improving HIV-related knowledge, attitudes, and behaviors. Addresses sexual behaviors related to pregnancy prevention, including avoiding risky situations, using condoms, and being monogamous. Participants learn the risks of IV drug use and unsafe sexual behaviors.</p> <p>Single-session, 5-hour, 6-part intervention. Small group discussion in groups of 6 to 12. Videos, role-plays, games and exercises reinforce learning and encourage participation.</p> <p>The program is culturally appropriate for inner city, black youth. It builds on young people's sense of community and addresses the importance of protecting one's community, as well as oneself, from the potential consequences of unprotected intercourse. The curriculum addresses youth's self-esteem and self-respect by emphasizing that it feels good to make proud and responsible safer sex choices.</p>	<p>Evaluation</p> <p>Experimental design – random assignment to treatment and control conditions. Control condition was career opportunities workshop.</p> <p>Pretest, immediate posttest, and three-month follow-up survey</p> <p>Urban black male teens (n=157) recruited from outpatients at a medical clinic in Philadelphia, a local high school and YMCA. Mean age 14.6</p> <p>Results: Reduced frequency of sex Reduced number of sexual partners Reduced number of female partners also involved with other men Increased condom use Reduced incidence of heterosexual anal intercourse</p>	<p>Materials</p> <p>Manual, activity set and session clips for \$95.</p> <p>Videos: <i>The Subject is: HIV</i> \$118 <i>AIDS Not Us</i> \$90.</p> <p>Full package: \$293</p> <p>Select Media 1-800-707-6334 www.selectmedia.org.</p>

Reducing the Risk	Target Population	Program	Evaluation	Materials
<p>Kirby D, Barth RP, Leland N <i>et al.</i> <u>Reducing the Risk: Impact of a New Curriculum on Sexual Risk-Taking.</u> <i>Family Planning Perspectives</i> 1991; 23(6):253-263.</p> <p>Hubbard BM, Giese ML, Rainey J. A Replication Study of <u>Reducing the Risk</u>, a Theory-Based Sexuality Curriculum for Adolescents. <i>Journal of School Health</i> 1998; 68:243-247.</p>	<p>Teens in high schools and community-based organizations</p>	<p>16-session sexual education curriculum based on social learning theory, social inoculation theory and cognitive behavior theory.</p> <p>Aims to reduce frequency of unprotected intercourse through delaying or reducing the frequency of intercourse; or increasing contraceptive use.</p> <p>Intended to serve as one component of a family life education course, rather than as a stand-alone program. Lessons are reinforced through role-plays, homework activities, quizzes and skill-building activities.</p> <p>The program aims to change student norms about unprotected sex and perceptions of peer sexual activity, as well as to strengthen parent-child communication about abstinence and contraception. The curriculum emphasizes that students should avoid unprotected intercourse, either by not having sex or by using contraception.</p>	<p>(1991 study.) Quasi-experimental evaluation conducted in 13 California high schools.</p> <p>Health education classes randomly assigned to treatment and control groups. Pretest, immediate post-test, and follow-up at 6 and 18 months.</p> <p>Participants: 758 high school students; mean age 15. 47% male. 61% white, 21 % Hispanic, 9% Asian, 2% African American.</p> <p>Results: Significant increases in teens' knowledge and communication with parents regarding abstinence and contraception.</p> <p>Among students who had not had intercourse at baseline: significant reduction in the likelihood of sexual debut by the 18-month follow-up.</p> <p>No effect on frequency of sexual intercourse or the use of contraceptives among teens who were sexually experienced at baseline.</p> <p>Among lower-risk youth and youth who were sexually inexperienced at baseline, the program reduced unprotected sex, either by delay of sexual debut or by increasing contraceptive use.</p> <p>(1998 study: quasi-experimental design with 18 month follow-up, in rural high school context. Program effects included delay in sexual debut and increased use of contraception among sexually active subjects.)</p>	<p><i>Reducing the Risk</i> Teacher's Manual (4th edition) + one Student Workbook: \$42.95</p> <p>ETR Associates</p>

Project SAFE	Target Population	Program	Evaluation	Materials
<p>Shain RN, Piper JM, Newton ER, et al. A Randomized, Controlled Trial of a Behavioral Intervention to Prevent Sexually Transmitted Disease Among Minority Women. <i>N Engl J Med</i> 1999;340:93-100.</p> <p>Shain RN, Perdue ST, Piper JM, et al. Behaviors Changed by Intervention are Associated With Reduced STD Recurrence: The Importance of Context in Measurement. <i>Sexually Transmitted Diseases</i>. Sept. 2002;29(9):520-529.</p> <p>Contact: Rochelle Shain, PhD Dept. of Ob/Gyn Univ. of Texas Health Science Center shain@uthscsa.edu</p>	<p>African American and Hispanic adult women</p>	<p>Gender- and culture- specific behavioral intervention to prevent STIs. Based on AIDS Risk Reduction Model, which suggests that 3 important stages in risk reduction are: a) recognition of one's risk; b) commitment to risk reduction; and c) acting on this commitment by seeking solutions. Passage from one stage to next requires understanding of disease transmission, sense of personal susceptibility, perception of costs and benefits of behavior change, self-efficacy and skill attainment.</p> <p>3 small-group sessions, 3-4 hours each; 3 consecutive weeks. 5-6 participants and female facilitator of same race/ethnicity.</p> <p>Session 1: Risk recognition. Prevalence of STIs in minority communities, addressing HIV/STI myths, begin building feelings of self-efficacy and power to control one's life, discuss selection of sex partners, information about STIs, increase awareness of personal risk.</p> <p>Session 2: Commitment to change. Information about STI prevention, importance of early treatment, compliance with treatment protocols, observing symptoms in partners. What to ask partners about current behavior and history. Barriers to condom use, how to overcome these barriers, erotic application of condoms. What women want in relationships, and why they may tolerate poor behavior from partners. Decisionmaking skills.</p> <p>Session 3: Skill acquisition. Communication/negotiation skills, with emphasis on ways to minimize threats to male self-esteem. (videos, role play with male facilitator). For Latina participants: discussion of how to use the concept of "machismo" to convince partners to be responsible lovers. Triggers for unsafe sex, goal-setting, acknowledgement of problems of economic and physical survival.</p> <p>(See 1st article for full list of session objectives/content.)</p>	<p>Randomized controlled trial. Subjects interviewed and screened for infection at baseline, 6 mo and 12 mo. Subjects stratified by race/ethnicity and randomized to treatment and control groups.</p> <p>Control group received standard counseling about STIs.</p> <p>424 Mexican-American and 193 African American women with current nonviral STDs, recruited from San Antonio public health clinics. Mean age: 21.8 yrs (intervention) and 21.3 yrs (control).</p> <p>Results: Rates of infection with CT and NG (Gen-Probe PACE 2 assay) were lower in intervention group than control during the first 6 mo of follow-up, the second 6 mo, and the full 12 mo follow-up period (16.8% vs. 26.9%).</p>	<p>We have this curriculum.</p>

Project SAFE II Shain RN, Piper JM, Holden A, et al. Prevention of Gonorrhea and Chlamydia Through Behavioral Intervention: Results of a Two-Year Randomized Controlled Trial in Minority Women. <i>Sexually Transmitted Diseases</i> . July 2004;31(7):401-408.	Target Population African American and Hispanic women	Program An enhanced Project SAFE intervention, consisting of Project SAFE + 5 optional monthly support group sessions after the main program. Each support group session: 90 min. <u>Support group discussion topics:</u> 1. Can I really get AIDS? (discussion on changing partners' behavior, ways to increase condom use, effects of alcohol/drugs on behavior) 2. Emotional and physical abuse, past and present 3. Sexual abuse and its relationship to STIs 4. Male and female social and sexual roles 5. Love, trust and intimacy (included discussion on settling for less than near-optimal intimacy, multiple relationships and misplaced trust)	Evaluation Randomized controlled trial. 3 arms: Project SAFE; Project SAFE plus 5 support groups; and control (baseline STI counseling session only). 775 African American and Mexican American women diagnosed with a nonviral STI in public health clinics. Ages 15-45. Participants were counseled and interviewed at baseline. Participants were subsequently interviewed, examined, screened for infection (Gen-Probe PACE 2), and treated when indicated at 6 mo., 1- and 2- year intervals. <u>Results:</u> Both risk reduction interventions significantly decreased both single and multiple infection episodes with CT and/or NG over the 2 year follow-up period. Support group attendance was associated with additional risk reduction in year 1, as well as with the greatest decrease in likelihood of multiple infections over the 2 year follow-up.	Materials For \$195: 1 PASHA User's Guide 1 Instructor's Handbook 3 Pamphlets for use as handouts (Making Sex Safer; Sexually Transmitted Diseases: What Everyone Should Know; HIV Infection and AIDS: What Everyone Should Know) 1 Set of Original Evaluation Instruments 1 Prevention Minimum Evaluation Data Set (PMEDS)
Safer Sex Efficacy Workshop Basen-Engquist, K. Evaluation of a theory-based HIV prevention intervention for college students. <i>AIDS Education & Prevention</i> . Oct 1994; 6(5): 412-424.	Target Population Though originally implemented in a college setting, the program is also suitable for use with young adults ages 18-22 in other educational settings or CBOs.	Program Three-hour HIV/STI prevention workshop based on social learning theory. Designed to increase college students' self-efficacy regarding their ability to prevent HIV and other STIs. The program includes numerous role-play and skill-building exercises, and is led by peer educators who are trained to serve as persuasive models. Program begins with a group discussion about HIV and other STIs, including transmission and prevention. Participants then discuss personal experiences and feelings about HIV and other STIs. Finally, participants role-play safer-sex discussions and learn about correct condom use, gaining confidence in their abilities in the process.	Evaluation A field study of the workshop was conducted with 209 undergraduate students enrolled in a health education class at the University of Texas. Mean age 22 years; 67% female; 82% white Treatment and comparison group; 2-month follow-up. <u>Results:</u> Increase in condom use frequency among sexually active participants, compared to comparison subjects Significant increases in participants' self-efficacy at follow-up, compared to comparison subjects.	

<p>Project RESPECT</p> <p>Kamb, M.L., Fishbein, M., Douglas, J.M., Rhodes, F., et al. Efficacy of Risk-Reduction Counseling to Prevent Human Immunodeficiency Virus and Sexually Transmitted Diseases: A Randomized Controlled Trial. <i>JAMA</i> 1998;280(13):1161-1167.</p> <p>Contact: Ken Hunt Centers for Disease Control and Prevention (404) 639-2058 khunt@cdc.gov</p>	<p>Target Population</p> <p>Heterosexual, HIV-negative adults attending STD clinics</p>	<p>Program</p> <p>HIV/STI prevention program based on the theory of reasoned action and social cognitive theory.</p> <p>Interactive counseling sessions were designed to change factors that could facilitate condom use - such as self-efficacy, attitudes and perceived norms.</p> <p>Enhanced Counseling intervention: 4 sessions; total of 200 minutes; completed in 3-4 weeks.</p> <p>Session 1: Assessed personal risk, identified barriers to risk reduction, negotiated a risk-reduction step achievable in the next week.</p> <p>Session 2: Explored condom use attitudes, discussed prior week's behavior change successes and barriers, developed a strategy for taking a risk-reduction step before the next session.</p> <p>Session 3: Received HIV test results, discussed prior week's behavioral goal and condom use barriers and facilitators, built condom use self-efficacy, developed strategy for taking another risk-reduction step.</p> <p>Session 4: Explored social norms and support for condom use, discussed prior week's behavioral goal successes and barriers, and developed long-term strategy for consistent condom use.</p> <p>Brief Counseling intervention: 2 sessions; total of 40 minutes; completed in 7-10 days. Based on the HIV Prevention Counseling protocol recommended by CDC for use with HIV testing since 1993.</p> <p>Session 1: Same as Session 1 above.</p> <p>Session 2: Provided HIV test results, discussed behavioral changes, provided support for changes made, discussed barriers and facilitators to change, developed a long-term plan for risk reduction.</p>	<p>Evaluation Randomized controlled trial.</p> <p>Arm 1 received enhanced counseling intervention; Arm 2 received brief counseling intervention; Arms 3 and 4 received 2 brief didactic messages typical of current care in STD clinics.</p> <p>Arms 1, 2 and 3 were followed up with questionnaires at 3, 6, 9 and 12 mo. STI tests/exams conducted at 6 and 12 mo (CT, NG, HIV, syphilis)</p> <p>5,758 heterosexual, HIV-seronegative adults attending inner-city STD clinics in Baltimore, Denver, Long Beach, Newark, and San Francisco. 57% male; 59% African American, 19% Hispanic, 16% white, 6% other. Median age: 25 yrs. 54% unemployed.</p> <p>Intervention delivered by health department staff, trained to conduct HIV counseling.</p> <p>Results: At 3 and 6 months, significantly more participants in both counseling interventions reported 100% condom use than control participants.</p> <p>At 6 months, 30% fewer counseling participants had new STIs than control participants.</p> <p>At 12 months, 20% fewer intervention participants had new STIs compared to control participants.</p> <p>Intervention effects on STD reduction were similar for men and women. Greater STD reductions for adolescents and subjects with an STI at baseline.</p> <p>Comparable effects overall for short and longer version of program.</p>	
--	--	--	---	--

<p>Project LIGHT</p> <p>NIMH Multisite HIV Prevention Trial Group. The NIMH Multisite Prevention Trial: Reducing HI Sexual Risk Behavior. <i>Science</i>. June 1998; 280(5371):1889-94.</p> <p>NIMH Multisite HIV Prevention Trial Group. Conceptual Basis and Procedures for the Intervention in a Multisite HIV Prevention Trial. <i>AIDS</i>. Feb 1997; 11 Supp 2:S29-S35.</p>	<p>Target Population</p> <p>Adults at high risk for HIV/STI based on sexual behavior, served in STD clinics and health service organizations</p>	<p>Program</p> <p>HIV prevention program, based on social cognitive theory and the theories of reasoned action and planned behavior.</p> <p>7 sessions, 90-120 min each. Met 2x/week in groups of 5-15 participants. Groups were separated by sex; co-lead by a female and male facilitator.</p> <p>Main factors targeted: outcome expectancies, skills, self-efficacy. Participants practice skills specific to their risk circumstances.</p> <p>Session 1 objectives: ground rules, myths/facts about HIV/AIDS, identifying personal values & reasons to stay healthy, identifying one personal risk factor for HIV, begin to learn about AIDS prevention strategies</p> <p>Session 2) Video of HIV+ person similar to participants. Discussion of personal vulnerability to HIV; defining triggers for risk situations; identification of a past incident of sexual risk behavior, a personal risk trigger, and a personal goal for next session.</p> <p>Session 3) Apply HIV risk reduction problem solving model to various hypothetical situation that require handling of risk triggers. Teaching of self-reward strategies.</p> <p>Session 4) Identify advantages of condom use; continuum of risk for sexual activities; proper placing and removal of male and female condoms; proper needle-cleaning</p> <p>Session 5) Practice of culturally appropriate sexual communication/negotiation strategies</p> <p>Session 6) Dealing with partner objections to safer sex; HIV testing with partner as a preventive strategy; further strategies for refusing unprotected sex – including strategies for negotiating with potentially abusive men.</p> <p>Session 7) Identify situations that could lead to relapse; dealing with potential relapse situations; self-rewards for maintaining safer sex behavior; ways to make safer sex more enjoyable; renewing or making commitment to safer sex practices.</p> <p>Each session began and ended with goal review and goal setting. Graduation from program was marked with diplomas, party and renewed commitment to safer sex.</p>	<p>Evaluation Randomized controlled trial with high-risk populations at 37 clinics from 7 U.S. cities. Baseline survey and follow-up at 3, 6 and 12 months.</p> <p>Subjects were men and women recruited from STD clinics (age 20+), and women recruited from health service organizations (age 18+). All subjects had recently engaged in sexual risk behavior. 74% African American; 73% had ever had an STD.</p> <p>Intervention group n=1851; control group n = 1855. Control condition had 1-hr AIDS education session that included a video and q/a period.</p> <p>Results: Compared to controls, intervention participants reported fewer unprotected sexual acts, had higher levels of condom use, and were more likely to use condoms consistently over the 12-month follow-up period.</p> <p>Among men recruited from STD clinics, intervention participants had 50% lower incidence rate of gonorrhea at 12 months as compared to controls (LCR).</p> <p>No difference in STD reinfection rate between intervention and control groups, based on chart review.</p>
--	---	--	---

Street Smart	Target Population	Program	Evaluation (2003 study)	Materials
<p>Rotheram-Borus MJ, Koopman C, Haignere C, et al. Reducing HIV Sexual Risk Behavior among Runaway Youths. <i>JAMA</i>. 1991;266:1237-1241.</p> <p>Rotheram-Borus MJ, Song J, Gwadz M, et al. Reductions in HIV Risk Among Runaway Youth. <i>Prevention Science</i>. Sept 2003;4(3):173-187.</p> <p>Contact: Mary Jane Rotheram-Borus, PhD Dept. of Psychiatry UCLA (310) 794-8278 rotheram@ucla.edu</p>	Homeless adolescents	<p>HIV prevention program based on social learning theory.</p> <p>10 group sessions 3x/wk, and 1 individual counseling session.</p> <p>Used small groups as practice and role-play opportunities; to mobilize and reinforce positive behaviors; and to maintain support networks.</p> <p>The intervention had four primary components:</p> <ol style="list-style-type: none"> 1. HIV-related knowledge. Activities included video and art workshops where youth developed soap opera skits, PSAs and raps about HIV prevention, and reviewed and discussed commercial HIV prevention videos. 2. Social skills. Training on assertiveness and coping skills, including ability to identify and self-regulate emotional states in situations with potential risk for HIV transmission. Subjects were taught self-regulation skills to control feelings of anxiety, depression, anger and desire. Addressed subjects' unrealistic expectations regarding their emotional and behavioral responses in high-risk situations. 3. Access to resources. Participants visited a community-based health and mental health center 1x/wk. Condoms were regularly available. 4. Personalized beliefs, attitudes and norms. Participants had a private counseling session addressing their individual barriers to practicing safer sex, and discussing their attitudes and behavior patterns. 	<p>Quasi-experimental design. 4 shelters for runaway adolescents in NYC area were assigned to treatment or control condition. Subjects assessed at baseline, 3, 6, 12, 18 and 24 months.</p> <p>Control condition: Usual care in shelter. Shelter staff received HIV prevention training from researchers.</p> <p>311 runaway and homeless youth. 51% male. 59% African American, 26% Hispanic. Mean age: 16 yrs.</p> <p>Results: Compared to female control subjects, female intervention participants had significant reductions in unprotected sexual acts at 2 years, and in alcohol use, marijuana use and the number of drugs used over 12 months.</p> <p>Male intervention group participants had significant decreases in marijuana use over 6 months, as compared to control group males.</p>	We have this curriculum.

DiClemente RJ, Wingood GM. A Randomized Controlled Trial of an HIV Sexual Risk-Reduction Intervention for Young African-American Women. JAMA. Oct 1995;274(16):1271-1276.	Target Population Heterosexual, young adult African American women	Program HIV prevention intervention. Main objective: to increase consistency in condom use 5 sessions, 2 hrs each Social skills intervention emphasizing gender and ethnic pride, based on social cognitive theory and the theory of gender and power. The latter theory examines the sexual division of labor, the sexual distribution of power/authority, etc. Within HIV prevention context, the theory leads to consideration of how women's relative power, commitment to a relationship, and frequent role in heterosexual relationships can affect their willingness to employ sexual risk-reduction strategies. Session 1: Emphasizes gender and ethnic pride. Values clarification; identifying personal African American women role models. Session 2: Discussion of HIV risk behaviors and preventive strategies. Used video that encourages women to take responsibility for sexual choices. Session 3: Sexual assertiveness & communication training. Modeling and role plays with feedback. Session 4: Condom use skills (modeling and practice with feedback); reinforcement of perception of consistent condom use as normative. Session 5: Promotion of cognitive coping skills (e.g., sexual self-control, communicating with noncompliant partner) through cognitive rehearsal.	Evaluation Randomized, single-blind controlled trial with pretest and 3-month post-test. 128 sexually active, heterosexual African American women ages 18-29 were recruited via street outreach in Bay View/Hunter's Point area. Randomly assigned to treatment group; 1-session HIV risk-reduction condition; or delayed HIV education control condition. <u>Results:</u> Compared with the delayed education control condition, intervention participants had increased consistent condom use, greater sexual self-control, greater sexual communication, greater sexual assertiveness, and increases in partners' adoption of norms supporting consistent condom use.	
---	--	---	---	--

<p>SHILE – Sistas, Informing, Healing, Living, Empowering</p> <p>DiClemente RJ, Wingood GM, Harrington KF. Efficacy of an HIV Prevention Intervention for African American Adolescent Girls: A Randomized Controlled Trial. <i>JAMA</i>. July 14, 2004;292(2):171-179.</p>	<p>Target Population</p> <p>African American adolescent girls</p>	<p>Program</p> <p>Objective: To reduce sexual risk behaviors, HIV/STIs and pregnancy, and to enhance mediators of HIV-preventive behaviors</p> <p>Based on social cognitive theory and the theory of gender and power.</p> <p>4 four-hour group sessions, 1x/week.</p> <p>Session 1: Emphasized gender and race/ethnic pride</p> <p>Session 2: Enhanced awareness of HIV risk-reduction strategies including abstinence, consistent condom use and fewer sex partners</p> <p>Session 3: Communication and negotiation skills, with role play and cognitive rehearsal. Peer educators modeled condom skills.</p> <p>Session 4: Discussion of healthy relationships, and how unhealthy relationships can impede practice of safer sex. Includes discussion of forms of relationship violence.</p>	<p>Evaluation</p> <p>Randomized controlled trial. At baseline, subjects completed questionnaire, interview, demonstrated condom application skills, gave specimens for STI testing. Follow up at 6 and 12 months, with collection of same data.</p> <p>Control condition: general health promotion program, of same duration as intervention</p> <p>522 sexually experienced African American girls ages 14-18, recruited from community health agencies.</p> <p>Implemented at a family medicine clinic by a female, African American health educator and 2 African American peer educators.</p> <p><u>Results:</u> Over the 12-month follow-up, intervention participants were more likely to use a condom at last sex, less likely to have had a new vaginal sex partner in past 30 days, and more likely to apply condoms to new partners. Participants also had better condom application skills, a higher percentage of condom-protected sex acts, fewer unprotected vaginal sex acts, higher scores on measures of mediators, lower likelihood of self-reported past 30-day pregnancy, and lower likelihood of chlamydia incidence.</p>	<p>Materials</p> <p>We have this curriculum.</p>
<p>Project Connect</p> <p>El-Bassel N, Witte SS, Gilbert L, et al. The Efficacy of a Relationship-Based HIV/STD Prevention Program for Heterosexual Couples. <i>Am J Public Health</i>. 2003;93:963-969.</p>	<p>Target Population</p> <p>African American and Latino adults involved in heterosexual relationships</p>	<p>Program</p> <p>HIV/STI prevention program, based on AIDS Risk Reduction Model and an ecological perspective. Program is also based partly on the idea that individuals acting unilaterally to introduce safer sexual practices in a relationship may meet with negative reactions from partner – including isolation, threats to end relationship, or violence.</p> <p>Objectives: to increase condom use, decrease STI transmission, and reduce the number of sexual partners among heterosexual couples, as compared to control group couples.</p> <p>1 individual orientation session + 5 two-hour group sessions</p> <p>Program emphasized importance of relationship communication, negotiation and problem-solving skills, and included discussion of how relationship dynamics can be affected by gender roles/expectations. The program also emphasized each couple's contribution to enhancing the future health of ethnic communities affected most by HIV/AIDS. Discussed hierarchy of safer sexual behaviors, joint HIV testing.</p>	<p>Evaluation</p> <p>Randomized controlled trial. Women ages 18-55 in long-term relationships with high-risk partners were recruited from hospital-based outpatient clinics in Bronx, NY; the women then recruited their partners.</p> <p>217 couples were randomized to a) 6 sessions for couples together (n=81); b) same program content/duration for women alone (n=73); or c) 1-session control condition for women alone (n=63).</p> <p>Pretest, and posttest at 3-month follow-up, for both women and men.</p> <p><u>Results:</u> significant reduction in proportion of unprotected sexual acts, and significant increase in proportion of protected sexual acts.</p> <p>No significant differences in effects of intervention for couples together vs. women alone.</p>	

Project FIO (The Future is Ours)	Target Population	Program	Evaluation
<p>Ehrhardt AA, Exner TM, Hoffman S, et al. A Gender-Specific HIV/STD Risk Reduction Intervention for Women in a Health Care Setting: Short- and Long-Term Results of a Randomized Clinical Trial. <i>AIDS Care</i>. 2002;14:147-161.</p> <p>Hoffman S, Exner TM, Leu CS, et al. Female Condom Use in a Gender-Specific Family Planning Clinic Trial. <i>Am J Public Health</i>. Nov 2003;93(11):1897-1903.</p> <p>Melendez RM, Hoffman S, Exner T, et al. Intimate Partner Violence and Safer Sex Negotiation: Effects of a Gender-Specific Intervention. <i>Arch Sexual Behav</i>. Dec 2003; 32(6):499-511.</p>	<p>Heterosexually active adult women utilizing family planning clinics</p>	<p>HIV/STI prevention program. Main objective: to reduce incidence of unprotected vaginal and anal intercourse.</p> <p>Based on modified (gender-specific) AIDS Risk Reduction Model.</p> <p>2-hour, small group sessions; 1x/wk. 2 female facilitators; at least one matched the ethnic background of the majority of participants (black or Latina).</p> <p>Session topics: 1) Why should I care about getting STDs and HIV? 2) How do I avoid partners who don't care? 3) What's the best way to protect myself? 4) How can I find out if we are infected? 5) How do I ask my partner to use protection? 6) How do I influence my partner to use protection? 7) How do I refuse sex or unprotected sex? 8) How do I continue protecting myself and others?</p> <p>Program was rooted in message of women's control over their sexuality. ½ of sessions addressed negotiation skills. Several sessions dealt specifically with issues related to abusive partners, including discussion of how to identify characteristics of men who don't care about women's needs in relationships; sexual rights; understanding how gender myths can impede women from taking self-protective action; dealing with a partner who becomes angry when asked to use a condom.</p>	<p>Randomized controlled trial.</p> <p>Study 1: Purpose: Evaluation of overall program effects on main study outcome of unprotected sex.</p> <p>360 women ages 18-30, who reported past-year heterosexual activity, no past-year IV drug use, and were not pregnant. 72% African American. Recruited from waiting room of Planned Parenthood clinic.</p> <p>Randomized to 4- or 8- session intervention group or non-intervention control group. Follow-up at 1, 6 and 12 months.</p> <p>Results: Participants in 8-session intervention were significantly more likely than controls to report maintaining consistent safer intercourse practices or decreasing the number of unprotected intercourse events – at 1-mo and 12-mo follow-up.</p> <p>Study 2: Purpose: to examine effects of intervention on attitudes toward and use of the female condom (n=360).</p> <p>Results: At 1 month, ORs of first-time female condom use were 9.5 (95% CI 4.0-22.2) in the 8-session group and 4.4 (1.8-10.5) in the 4-session group, as compared to control group. There was no longer-term effect of intervention on FC use (at 6 or 12 mo). Repeated FC use was predicted by perceived ability to use, self and partner satisfaction, dislike of male condoms, and prior diaphragm use.</p>
		<p>Female condom (FC): Participants practiced inserting the FC into a pelvic model. Advantages and potential difficulties associated with the FC were discussed. Women were given FCs and encouraged to try using them. Women subsequently discussed their experiences with the FC and how to overcome challenges with use. In subsequent sessions, participants enacted ways in which to introduce both M and F condoms to new and established partners. FCs were available at other sessions.</p>	<p>Study 3: Purpose: to examine effects of intervention among participants who reported physical abuse by current or past-year intimate partner (subgroup analysis; n=152).</p> <p>Results: Women in the 8-session, but not the 4-session, intervention had fewer incidents of unprotected sex at 1 month (OR 3.63, 95% CI 1.5-8.8) and 1 year (OR 2.9; 1.2-7.1) post-intervention. At 1 month, 4- and 8-session participants had greater likelihood than controls of using protective strategies (refusal, intercourse, mutual testing, etc.) and of having safer sex discussion with partner. No effect of intervention on reported incidence of abuse in follow-up year.</p>

<p>Scholes D, McBride CM, Grothaus L, et al. A Tailored Minimal Self-Help Intervention to Promote Condom Use in Young Women: Results from a Randomized Trial. <i>AIDS</i>. July 2003;17(10): 1547-1556.</p>	<p>Target Population</p> <p>Young adult women at risk of STI</p>	<p>Program</p> <p>Self-help intervention based on AIDS Risk Reduction Model, Stages of Change, Theory of Reasoned Action</p> <p>Objective: to increase condom use over a 6-month period.</p> <p>After a baseline survey (content not described), participants received two rounds of individually tailored materials by mail. They first received a tailored, 12-page, self-help magazine-style booklet and a safe sex kit containing male and female condoms, a condom carrying case, and instructions on condom use. The booklet was accompanied by a letter informing participants that the materials had information especially for them, based on their answers to the recent women's health survey.</p> <p>There were 4 generic booklet sections and 7 tailored sections; the most extensively tailored sections were an advice column and testimonial stories.</p> <p>After 3 month-follow-up survey, participants received a tailored booster feedback newsletter (based on responses to the 3-month survey) and condom packet. Newsletter focused on removing barriers and enhancing facilitators to condom use.</p> <p>Investigators created a library of tailored messages, and algorithms were developed that selected and formatted the tailored message based on participants' responses to particular survey items.</p> <p>Constructs used in tailoring included stage of readiness to adopt condom use, beliefs and perceived norms re condom use, intentions and efficacy to use condoms, perceived barriers/facilitators to use condoms, perceived STI risk and type of partner (primary, non-primary).</p>	<p>Evaluation</p> <p>Randomized controlled trial with subjects from 2 managed care plans in WA and NC. Follow-up at 3 and 6 mo. Control group received usual care.</p> <p>Sample: 1,210 heterosexually active, nonmonogamous, unmarried, non-pregnant women, ages 18-24, who had made a clinic visit in prior 5 months. 31% non-white; 27% had history of STI.</p> <p>6-month results: Intervention participants had significantly more condom use overall and with recent primary partners than control group (in prior 3 months).</p> <p>Intervention participants used condoms for a greater proportion of intercourse episodes than controls.</p> <p>More intervention participants carried condoms, discussed condoms with partners and had higher self-efficacy to use condoms with primary partners than controls.</p>	
---	---	--	--	--

<p>Jaworski BC, Carey MP. Effects of a Brief, Theory-Based STD-Prevention Program for Female College Students. <i>J Adol Health</i>. Dec 2001;29(6):417-425.</p>	<p>Target Population</p> <p>Female college students</p>	<p>Program</p> <p>Single-session STI risk-reduction intervention.</p> <p>Based on IMB model. Also used a motivational-enhancement approach, which has 5 therapeutic principles: 1) facilitators express empathy for participants; 2) program leads to increased awareness of discrepancy between stated safety goals and actual risk behavior; 3) argumentation is avoided; 4) facilitators "roll with" resistance; 4) self-efficacy is supported.</p> <p>Segment 1: introduction to group rules.</p> <p>Segment 2: informational and motivational components. Statistics on STIs among college women, personalized risk feedback based on participants' risk behaviors and data from a normative sample of women at the same college.</p> <p>Segment 3: Elicitation of risk-reduction strategies from participants; discussion of pros and cons; emphasis on the advantages. Discussion of barriers and ways to address them.</p> <p>Segment 4: Exercises to improve safer sex communication skills using role plays.</p> <p>Segment 5: Participants complete and share action plans.</p> <p>Facilitators then summarize the various components of the session, skills learned and participants' commitments to change, and reinforced participants' ability to realize risk-reduction strategies (30 min).</p>	<p>Evaluation</p> <p>78 undergraduate women (mean age 20 yrs; 76% white) randomly assigned to one-session intervention based on IMB model, one-session information-only intervention; or wait-list control group. Immediate and two-month post-test.</p> <p>At immediate post-test, both IMB and info-only groups had increased STI-related knowledge.</p> <p>At 2 mo. follow-up, both groups had sustained their knowledge levels, and the IMB group showed had a reduced number of sexual partners as compared to the wait list control group.</p> <p>No program effect on participants' condom attitudes, intentions to engage in risk-reducing behavior, communication skills or condom use.</p>	
<p>O'Donnell CR, O'Donnell L, Doval AS, et al. Reductions in STD Infections Subsequent to an STD Clinic Visit: Using Video-Based Patient Education to Supplement Provider Interactions. <i>Sexually Transmitted Diseases</i>. March 1998;25(3):161-168.</p> <p>Contact: Carl O'Donnell, ScD. Beth Israel Deaconess Medical Center</p>	<p>Target Population</p> <p>African American and Hispanic men attending STI clinics</p>	<p>Program</p> <p>Single-session STI prevention program presented to patients in waiting room at STI clinics.</p> <p>2 culturally appropriate videos were used: "Let's Do Something Different" for African American audiences and "Porque Si" for Hispanic audiences.</p> <p>Both videos: provide information and dispel misinformation about STIs and their prevention; portray positive attitudes about condom use; and model culturally appropriate strategies for encouraging condom use.</p> <p>In the subsequent interactive session, video served as trigger for discussion. The discussion reinforced the risks associated with unprotected sex. Participants discussed problems they had encountered trying to use condoms, and ways to overcome these barriers.</p> <p>All study subjects (tx and control) were offered free condoms and a coupon for free condoms at a local pharmacy.</p>	<p>Evaluation</p> <p>Randomized controlled trial. Random assignment to video-based intervention; video-based intervention followed by group discussion; or control group (regular clinic services).</p> <p>Follow-up: subjects were tracked for an average of 17 months for incidence of new STI infections, through New York City STD Surveillance database.</p> <p>2,004 African American and Hispanic men attending a public STI clinic in South Bronx. Mean age: 30 yrs.</p> <p><u>Results:</u> Rate of new infection over follow-up period was significantly lower for intervention participants than controls (22.5% vs. 26.8%).</p> <p>Among subjects reporting multiple sex partners at baseline, intervention participants had a lower infection rate than controls (24.8% vs. 32.2%).</p> <p>No difference in intervention effectiveness with vs. without post-video discussion.</p>	

Sexual Harassment, Sexual Assault and Dating Violence Prevention Programs – Summary Chart

Main sources:

- PsycInfo
- CDC National Center for Injury Prevention and Control <http://www.cdc.gov/ncipc>
- CDC National Electronic Network on Violence Against Women <http://www.vawnet.org>
- VAWnet – National Electronic Network on Violence Against Women (2002) <http://www.ualgary.ca/resolve/violenceprevention/English/reviewprog/youthdprog.htm>
- "Prevention Programs Addressing Youth Dating Violence."

Program	Target population	Program Content	Evaluation	Program Materials	Notes
MVP (Mentors in Violence Prevention) JacksonKatz@aol.com www.jacksonkatz.com Reconstructing masculinity in the locker room: The Mentors in Violence Prevention Project. (1995, Summer). Harvard Educational Review , Vol. 65, No. 2. Working with male student-athletes. (1993). In A. Parrot, N. Cummings & T. Marchell (Eds.), Rape 101: Sexual assault prevention for college athletes . Learning Publications. More than a few good men: Strategies for inspiring boys and young men to be allies in anti-sexist education. (1998). Working Papers Series . Wellesley, MA: Wellesley Center for Research on Women.	High school students, college athletes/other students, military personnel.	<p>MVP takes an "empowered bystander" approach to the prevention of gender-based violence (including harassment, sexual/physical assault, gay-bashing). The training focuses on scenarios and role-plays intended to allow students to construct and practice viable options in response to incidents of harassment, abuse, or violence before, during, or after the fact. Participants learn that there is not simply "one way" to confront violence, but that individuals can learn skills to build their resolve and to act when faced with difficult or threatening situations.</p> <p>MVP focuses on young men not as potential perpetrators, but as empowered bystanders who can confront abusive peers and support abused ones. It focuses on young women not as victims or potential targets, but as empowered bystanders who can support abused peers - and confront abusive ones. In this model, a "bystander" is defined as a family member, friend, classmate, teammate, coworker—anyone who is imbedded in a family, school, social, or professional relationship with someone who might in some way be abusive, or experiencing abuse.</p> <p>The program fosters interactive discussion, in single-sex and mixed-gender classes and workshops, using real-life scenarios that speak to participants' experiences.</p> <p>The main curricular innovation of MVP is a training tool called the Playbook, which consists of a series of realistic scenarios depicting abusive male (and sometimes female) behavior. (Number of sessions not specified. 13 scenarios.)</p> <p>The Playbook – with separate versions for men and women - transports participants into scenarios as witnesses to actual or potential abuse, then challenges them to consider concrete options for intervention before, during, or after an incident. With more options to choose from, people are more likely to respond and not be passive and silent regarding abuse.</p>	Qualitative evaluation only.	<p>MVP Playbook for High School Males</p> <p>MVP Trainer's Guide for Working With High School Males</p> <p>MVP Playbook for High School Females</p> <p>MVP Trainer's Guide for Working With High School Females</p> <p>MVP Playbook for College Males</p> <p>MVP Trainer's Guide for Working With College Males</p> <p>For four items: \$35.00 MVP Strategies, 3860 Brayton Ave, Long Beach, CA 90807</p> <p>We have the Marine Corps' Trainer's Guide, Advanced Trainer's Guide, and adapted Playbook.</p>	<p>This program has been adapted and implemented with groups of Marines for the past 7 years. Marine commanding officers have been trained as facilitators of the program for their commands. The adapted curriculum uses Marine scenarios and military language.</p> <p>Marine playbook scenarios address topics including battering, rape, alcohol and consent, sexual harassment, gang rape, self-defense, harassment of lesbians and gay men, and pressure for sex.</p>

Safe Dates	Target Population	Program	Evaluation	Materials	Note
<p>Foshee VA, Bauman KE, Ennett ST, Linder GF, Benefield T, Suchindran C. Assessing the long-term effects of the Safe Dates program and a booster in preventing and reducing adolescent dating violence victimization and perpetration. <i>American Journal of Public Health</i> 2004;94(4):619-624.</p> <p>Foshee VA, Bauman KE, Greene WF, Koch GG, Linder GF, MacDougall JE. The Safe Dates program: 1-year follow-up results. <i>American Journal of Public Health</i> 2000;90(10):1619-1622.</p> <p>Foshee VA, Bauman KE, Arriaga XB, Helms RW, Koch GG, Linder GF. An evaluation of Safe Dates, an adolescent dating violence prevention program. <i>American Journal of Public Health</i> 1998;88(1):45-50.</p> <p>Program Developer Ann Standing National Education Sales Manager Hazelnden Publishing and Education Services Phone: 651-213-4030 Email: astanding@hazelnden.org Web site: www.hazelnden.org</p>	<p>Middle- and high-school students.</p>	<p>Program Dating violence prevention program with five components: 9-session curriculum, play script, poster contest, parent materials, and teacher-training outline.</p> <p>9 50-minute sessions. Includes interactive exercises such as games, small- and large-group discussions, role-play, writing exercises. Can be delivered by teachers and counselors; some schools have trained student peer leaders who can teach or assist with program delivery.</p> <p>Session 1: Students use a game and discussion to evaluate how they want to be treated in dating relationships.</p> <p>Session 2: Students define dating abuse through the discussion of scenarios and statistics.</p> <p>Session 3: Students identify the causes and consequences of dating abuse through large- and small-group scenario discussions.</p> <p>Session 4: Students learn why it is difficult to leave abusive relationships and how to help an abused friend.</p> <p>Session 5: Students use stories and role-playing to practice skills for helping abused friends or confronting abusing friends.</p> <p>Session 6: Students learn about gender stereotypes and how they affect dating relationships.</p> <p>Session 7: Students learn skills for effective communication and practice these skills in role-plays.</p> <p>Session 8: Students learn effective ways to recognize and handle anger so that it does not lead to abusive behavior.</p> <p>Session 9: Students learn about sexual assault and how to prevent it through a quiz, a caucus and a panel of peers.</p> <p>Safe Dates includes a 45-minute play about dating abuse entitled, "There's No Excuse For Dating Abuse." The play, performed by students, can be presented at the beginning or the end of the program. Student actors can lead post-play small-group discussions using local statistics on dating abuse and other issues presented in the play. The poster contest reinforces the concepts learned in the curriculum.</p> <p>Safe Dates involves family members through its parent letter and parent brochure, which provides resources and information regarding teen dating abuse. Teachers are encouraged to connect with local community domestic violence and sexual assault resources.</p>	<p>Pre-/post-test control group experimental design. Students in grades 8 and 9 attending 14 schools in a primarily rural North Carolina county were stratified by grade and matched by school size. One school from each matched pair was randomly assigned to treatment condition and the other to a control condition.</p> <p>Baseline data was collected in schools from 81 percent of the eighth and ninth graders in the county (n = 1,886). Follow-up data was collected from self-administered questionnaires completed in schools 1 month and 1, 2, 3, and 4 years after program activities were completed. Extensive process data also was collected on program fidelity.</p> <p>Results: Significant reductions in psychological, moderate physical, and sexual dating violence perpetration, and significant reduction in moderate physical dating violence victimization at all follow-up periods, among intervention participants vs. controls.</p> <p>Marginal effect ($p = .07$) on sexual dating violence victimization at all follow-up periods.</p> <p>The program was equally effective for males and females. Program effects were mediated mainly by alterations in dating violence norms, gender-role norms, and awareness of community services.</p> <p>Program effects on almost all victimization and perpetration outcomes were maintained four years after program exposure, with treatment group outcome means ranging from 56% to 92% less than the control group means.</p>	<p>Curriculum, parent materials, teacher training outline, play script</p> <p>We have the curriculum.</p>	<p>the a viole progi follo years</p>

Scruples	Target population	Program	Evaluation	Materials	Notes
<p>Lanier CA, Elliott MV, Martin DW, et al. Evaluation of an Intervention to Change Attitudes Toward Date Rape. <i>J of American College Health</i>. Jan 1998;46(4): 177.</p>	<p>College students</p>	<p>Program One-hour play performed by students, focused on date rape prevention. Based on social learning theory and risk-factor reduction approach.</p> <p>Scene 1: Overview of characters; introduce role of alcohol in promoting rape</p> <p>Scene 2: Two male actors demonstrate communication skills in relationships; importance of obtaining explicit verbal consent; notion that a serious romantic relationship does not automatically imply sex – that abstinence is a viable choice.</p> <p>Scene 3: M and F actors. Demonstrate that an invitation to someone's home is not an invitation for sex.</p> <p>Scene 4: M and F actors. Male shows behavior "typical of a campus rapist by testing the limits of female (e.g., by intimately touching her to see how she would respond." Female notes that she has not consented to have sex and clearly objects to the behavior.</p> <p>Scene 5: Five M and F actors meet with a survivor of an attempted sexual assault to listen to her and support her choice to report the perpetrator.</p> <p>Scene 6: 2 male actors confront another male friend about his inappropriate behavior, providing positive role modeling regarding bystander behavior and male proactiveness.</p>	<p>Evaluation Randomized pretest and posttest control group design. Control condition was an alternative play on multicultural issues. Pre and post tests were given immediately before and after play.</p> <p>Goal: to assess change in attitudes regarding date rape, in context of heterosexual college dating.</p> <p>All incoming students of the 1995 class of an elite private university in Texas were invited to participate in the study. 71% (436) attended the program and completed the pre/post tests. Participants were 64.6% Caucasian, 9.4% Hispanic, 19.3% Asian American, 3.7% African-American.</p> <p>Results: Significant attitude improvement (.23 units on 5-point scale) was found for subgroup with lowest pretest scores for rape attitudes (bottom 25%, most rape tolerant). Even after intervention, however, scores for this subgroup remained below the full group average.</p> <p>Students scoring in the upper 75% at pretest showed modest improvement in attitudes (.05 units on 5-point scale) – possibly related to a ceiling effect.</p> <p>Men and women in treatment group did not differ in attitude improvement.</p>	<p>Materials</p> <p>Play script: Scruples (Bruckman L, Fowlkes T, Galloway S, et al. Scruples. Unpublished manuscript. Houston, TX: Rice University; 1995).</p>	<p>This is one of very few studies with an explicit basis in social learning concepts. Most sexual violence prevention studies do not cite the well-known cognitive-behavioral theories as frameworks.</p> <p>There was no opportunity for discussion after the play; discussion of videos/plays has been found to improve outcomes for this type of intervention.</p>

<p>The Men's Program</p> <p>Developer: John Foubert Office of the Dean of Students; (804) 924-3736 NOMORE@virginia.edu</p> <p>Foubert, JD. The Longitudinal Effects of a Rape-Prevention Program on Fraternity Men's Attitudes, Behavioral Intent and Behavior. <i>J of American College Health</i>. Jan 2000; 48(4):158-163.</p> <p>Also see discussion in Berkowitz A, "Fostering Men's Responsibility for Preventing Sexual Assault," in Schewe PA, Ed. <u>Preventing Violence in Relationships</u>. Washington D.C.: American Psychological Association. 2002.</p>	<p>Target population:</p> <p>College fraternity men</p>	<p>Program A rape prevention program for fraternity men, aimed at building empathy for female rape survivors. The presentation is entitled "How to Help a Sexual Assault Survivor: What Men Can Do."</p> <p>One-hour program, lecture/discussion format, with discussion of a video developed by the Seattle Police Dept. of a male officer raped by 2 other men.</p> <p>The program is designed to help men understand what it might feel like to be raped, so as to develop empathy for female victims.</p> <p>After showing the video, peer educators discuss the video as an act of violence (as opposed to sex) and draw parallels from the male police officer's experience to common experiences of female survivors.</p> <p>Participants are then taught basic skills on how to help a woman recover from rape. Men are encouraged to communicate openly in sexual encounters and to help change societal norms that promote rape. Presenters respond to questions.</p>	<p>Evaluation 8 of 23 fraternities on a mid-Atlantic public university campus volunteered to take part in the study. 4 fraternities each were randomly assigned to treatment (n=109) and control (n= 108; no alternative treatment) conditions. Within each group, 2 fraternities were assigned to pretest/posttest condition, and the other 2 were assigned to post-test only. Post-tests were given immediately after program, and again at longer-term follow-up.</p> <p>Results: At 7-month follow-up, intervention participants - as well as control group participants - demonstrated significant declines in rape myth acceptance and self-reported likelihood of committing rape (the latter was assessed by the question, "if you could be assured of not being caught or punished, how likely would you be to rape?")</p> <p>Reduction in self-reported intent to rape was not associated with reduction in actual levels of reported coercive behavior at 7-month follow-up. No evidence of change in coercive behavior was found.</p>	<p>Materials</p> <p>A peer educators' training manual (highly recommended by Alan Berkowitz) is available for free from J. Foubert.</p>	<p>Notes</p> <p>Berkowitz (2002) notes that the program draws on research suggesting that empathy-based programs are less effective for men when female victims are portrayed, and assumes that men will be able to transfer the empathy generated for the male officer to female survivors.</p> <p>Evaluation of this program has elicited controversy re interpretation of findings.</p>
<p>Fraternity Violence Education Project</p> <p>Developer: Deborah Mahlstedt, Dept. of Psychology, West Chester University, West Chester, PA. dmahlstedt@wcpa.edu</p>	<p>Target Population</p> <p>College fraternity men</p>	<p>Program</p> <p>A one-semester course on violence against women (VAW) for fraternity leaders, which provides an in-depth feminist analysis of male violence and power.</p> <p>Participants are trained in the first semester to present skits to fraternity members about male violence and sexual harassment. The peer-led workshops are then offered in the second semester, followed by a term paper evaluating the year-long experience.</p> <p>There is also a video used in the program entitled "Men's Work," which follows a group of fraternity brothers enrolled in the program over the course of the 1-year period. In the video, they explore causes of VAW, examine their own attitudes/behavior, and begin speaking with other men on campus about men's responsibility to stop VAW. Topics including sexual objectification, peer pressure, hypermasculinity & male institutional power are addressed. Each section ends with a discussion question. The video can be used in a variety of ways by other programs depending on context.</p>	<p>Evaluation</p> <p>Found no published studies</p>	<p>Materials</p> <p>Program manual and video. Manual contains outline of the training curriculum, workshop skits and exercises.</p>	

Rape Prevention Program For Men (RPPM)	Target population:	Program	Evaluation	Materials	Note
<p>Developed by Alan Berkowitz. (607) 387-3789. alan@fltg.net</p> <p>Earle JP, Acquaintance Rape Workshops: Their Effectiveness in Changing the Attitudes of First Year Men. <i>NASPA Journal</i>. 1996; 34(1):2-16.</p> <p>Davis TL (1997). The Effectiveness of a Sex Role Socialization-Focused Date Rape Prevention Program in Reducing Rape Supportive Attitudes in Fraternity College Men. Unpublished master's thesis, University of Iowa, Ames.</p> <p>Davis TL, 2000. Programming for Men to Reduce Sexual Violence. In D Liddel & J Lund (Eds). <i>Powerful Programs for Student Learning: Approaches That Make a Difference</i>. Pp 79-89. San Francisco, CA: Jossey-Bass.</p> <p><i>For a summary of the social norms approach and study findings, see: Berkowitz A, The Social Norms Approach: Theory, Research and Annotated Bibliography.</i></p>	<p>First-year college men</p>	<p>Has been offered as required workshop for first-year men at Hobart College since 1987. Approx. 2 hrs.</p> <p>Conducted by trained peer educators, with focus on group discussion/interaction.</p> <p>Based on scenarios that portray an intimate encounter between a male and female; men's discomfort with other men's language and behavior; and men's experience of pressure to be sexually active from other men.</p> <p>The program attempts to bring men's discomfort with the opportunistic and coercive sexual behavior of other men out into the open so that discomfort with such behavior can be shared and acted upon.</p> <p>The program also teaches guidelines for consenting sexual intimacy, and addresses issues including men's (false) fear of false accusation and developing empathy for sexual assault survivors.</p> <p>Program is based on Alan Berkowitz's social norms approach (salient in sexual assault literature), which suggests that people behave in accordance with perceived norms, even when these perceptions are wrong. Regarding violence against women, the social norms approach suggests that most men are against violence/harassment, but don't intervene or speak up when they see/hear something abusive because they don't feel like part of an empowered majority. Social norms approaches assume that the majority of men have positive feelings/attitudes, and aim to help men see that these are the norm through varying means (e.g., group discussions as in this program, or environmental interventions advertising research-based statements such as, "95% of men at X University believe it is wrong to..")</p>	<p>Earle 1996: This study compared the RPPM with two co-ed rape prevention programs and a nontreatment control group. One of the comparison programs used an interactive, small group format and the other was a large group lecture. Of the 3 interventions, only the RPPM produced positive changes in rape myth acceptance and attitudes toward women, in comparison with the control group. (Follow-up period?)</p> <p>Davis (1997, 2000) In these studies, the RPPM was compared with another small group, interactive rape prevention program that focused on male socialization issues.</p> <p>Both programs reduced rape-supportive attitudes and increased men's understanding of consent and coercion at post-test immediately after the workshop, but the improvements were not present at 6-week follow-up.</p>	<p>Sample workshop scenarios can be obtained from the author.</p> <p>We have the curriculum used to train peer educators.</p>	<p>There are various other intervention studies that support the use of social norms approaches to address issues such as substance abuse. The approach requires, however, that true norms really be against the risk behavior in question.</p>

<p>Heppner MJ, Neville HA, Smith K, et. Al. Examining Immediate and Long-Term Efficacy of Rape Prevention Programming with Racially Diverse College Men. <i>J of Counseling Psychology</i>. 1999;46(10):16-26.</p>	<p>Target population Black and white college men</p>	<p>Program Three 90-min sessions, held 1x/week. Based on Elaboration Likelihood Model (ELM) of attitude change, which distinguishes between attitude change/learning based on peripheral route processing vs. central route processing. When a participant feels the message of a program has high personal relevance, this increases the likelihood of real engagement, consideration of message, and more stable attitude change (central route processing). Another attitude change model (Eagly and Chaiken (1992) was also drawn upon, which states that attitudes can be inferred through observation of cognitions, affective expression and behavior. <u>Cognitive change module:</u> discussion of rape myths/facts, local stats on prevalence of acquaintance rape, definition of consent, legal definition of rape, video (content not described). <u>Affective change module:</u> panel of rape survivors discussing long-term effects of rape on their lives, as well as two males who had provided support to friends who had experienced rape. Goal: to increase empathy. <u>Behavior change module:</u> 2 role play scenarios: a) coercive dating scenario -- participants rewrite so coercion is avoided; and b) assisting a friend who has been raped. Culturally relevant experimental condition had one black facilitator, rape survivor panelist, male ally panelist, and role player. Specific factual info re rape among black and white populations, "race-related" rape myths, discussion of how race and culture can affect the affective response to rape.</p>	<p>Evaluation 119 men in large Midwestern university (28% black; 64% white; most white men in fraternities; half of black men in fraternities) Random assignment to non-intervention control group and two intervention groups (culturally relevant and "color-blind"). Pretest, immediate posttest, and 5-month post test. <u>Results:</u> For some program participants, significant decrease in rape-supportive attitudes at immediate post; effect maintained at 5 months. For others, decrease in rape supportive attitudes at immediate posttest, but attitudes rebounded to original level by 5 months. (No further analyses re who was in this group.) Black men in culturally relevant group reported being more engaged than black men in color-blind intervention. No "adverse effect" of culturally relevant program for white participants.</p>	
--	---	---	---	--

<p>Date Rape Prevention: A Video Intervention For College Students</p> <p>Developer: Northwest Media www.northwestmedia.com/health/daterape.html</p> <p>Program authors: Schewe PA, O'Donohue WT. Rape Prevention With High-Risk Males: Short-term Outcomes of Two Interventions. <i>Arch Sexual Behavior</i>. 1996; 25(5): 455-471.</p>	<p>Target population: Male college students</p>	<p>Program 50-min video addressing rape-supportive cognitions (RSC). Contains 3 segments, targeting dysfunctional cognitions suggested by the literature to be related to rape: adherence to rape myths, victim empathy, and perceived negative consequences of committing rape.</p> <p>Segment 1: portrays college students with varying viewpoints discussing a publicized rape that occurred on campus. This segment aims to provide the audience with more accurate information to replace widely held, rape-supportive beliefs.</p> <p>Segment 2: Several rape victims discuss their experience – for development of empathy among audience members.</p> <p>Segment 3: Portrayal of several men who have sexually coerced or raped women – to highlight negative consequences of assault for men.</p> <p>After the video, subjects are presented with a hypothetical man who believes he can force sex upon women when he wants to. Subjects then brainstorm ways in which they would try to convince this man to change his behavior.</p> <p>The segments can stand alone or be incorporated into other workshops.</p>	<p>Evaluation</p> <p>Randomized pre/post design with 2-week follow-up.</p> <p>Subjects were 74 college men who scored high (15 or more) on Attraction to Sexual Aggression Scale.</p> <p>Subjects were randomly assigned to one of 3 groups. The RSC video intervention (n=22) was compared to another video intervention focused on affecting victim empathy and rape outcome expectancies (n=26), and a no-treatment control group (n=26).</p> <p>Results: Participants who viewed the RSC video had significantly improved post-test scores on measures of rape myth acceptance, acceptance of interpersonal violence (attitudes condoning use of force in relationships) and attraction to sexual aggression at 2-week follow-up, as compared to subjects in the other two groups.</p>	
--	---	---	--	--

<p>"Tough Guise: Violence, Media, and the Crisis in Masculinity"</p> <p>Jackson Katz jacksonkatz@aol.com www.jacksonkatz.com</p>	<p>Target population:</p> <p>College students (mixed sex or male only groups).</p> <p>Has also been used in batterer intervention programs and other community settings.</p>	<p>Program 82 min. video used in conjunction with 22-page study guide. Can be used for single or multiple sessions.</p> <p>The video provides an analysis of the relationship between mass media, notions of masculinity, and violence (violence against women, gay-bashing, and among men) The goals include increasing an awareness of media's influence in perpetuating cultural norms of masculinity and violence, and providing participants with analytic tools to understand how media works.</p>	<p>Evaluation: No published studies.</p>	<p>Materials</p> <p>Video and study guide</p> <p>We have the study guide.</p>	<p>Note</p> <p>Video is well-known and widely used in high schools, colleges, batterer intervention programs, and gender violence prevention programs. Authors say it's been viewed by over 3 million people.</p>
<p>Holcomb DR, Savage MP, Seehafer R, et al. A Mixed-Gender Date Rape Prevention Intervention Targeting Freshmen College Athletes. <i>College Student Journal</i>. Jan 2002. 36(2); 165-179.</p>	<p>Target Population:</p> <p>Freshmen college athletes (m & f)</p>	<p>Program</p> <p>Duration: One class period. Program aims to address date rape stereotypes and rape-tolerant attitudes among college athletes.</p> <p>Content: Presentation and discussion of scenario of a male and female on a date, based on factors associated with the occurrence of date rape. Discussion focuses on determination of when and how consent to have sex occurs. The presenters define consent as having 2 components: 1) full understanding of all possible repercussions, which precludes either partner being intoxicated, and 2) true freedom to say yes or no (which rules out power differentials (e.g., teacher & student).</p> <p>After scenario, suggestions for preventing future rapes are presented by the facilitators, and students are asked to offer modifications to these suggestions.</p>	<p>Evaluation</p> <p>Randomized post-test only experimental design, comparing the date rape attitudes of freshman athletes who were exposed to intervention (n=56) to those of athletes not exposed (n=86).</p> <p>Post-test given immediately after intervention.</p> <p>The program was administered during a required health education course by 2 female instructors. Course sections were randomly assigned to treatment status.</p> <p><u>Post-test results:</u> Male athletes reported attitudes that were more tolerant of date rape than female athletes; intervention participants were less tolerant of date rape than control participants; and male athletes did not exhibit a greater program effect than females.</p>	<p>Materials</p> <p>Workshop script, brief training protocol, research design protocol.</p>	

<p>PAYS – Preventing Assault by Young Student Athletes</p> <p>Jackson TL, Davis JL. Prevention of Sexual and Physical Assault Toward Women: A Program for Male Athletes. <i>J Comm Psychology</i>. 2000. 28(6):589-605.</p>	<p>Target Population</p> <p>Male college athletes</p>	<p>Program “Rationally derived,” “pragmatic” 1.5 hour presentation given to athletic teams (duration can range from 20 min-2 hrs). Combination of lecture and discussion facilitated by slides and practice exercises, scenarios, role plays.</p> <p>The authors note that the culture of male college athletics promotes a win-at-all costs mentality, with a value system that emphasizes hypermasculinity, adversarial thinking, aggression, dominance and acting decisively in an almost automatic, instinctive manner.</p> <p>The program discusses how the same qualities rewarded on-field can be damaging to the athlete off-field (e.g., dominance on-field = intimidation off-field), and aims to teach the difference between appropriate on- and off- field behavior.</p> <p>Legal definitions and incidence rates of rape, sexual assault and physical assault are presented. The costs to costs to self (reputation, lose scholarship, athletic career), team, and university of being charged with or convicted of assault are emphasized. The latter emphasis is suggested to be useful given time constraints and the low probability of significant core value change. The victimization of males is also discussed, and participants are also encouraged to be their “brothers’ keeper” and pull them out of potential confrontations.</p> <p>The program attempts to increase empathy for assault victims by discussing consequences of assault to them and asking participants how they would feel if their sister or girlfriend was assaulted. Program also addresses sexual communication, consent, people’s right to refuse sexual interactions, body language, danger of mixing alcohol/drugs with intimacy, importance of walking away if a woman hits you to get your attention.</p> <p>Authors recommend male presenters, ideally with athletic background or otherwise seen as “powerful.”</p>	<p>Evaluation</p> <p>Mainly qualitative – through “self-report,” consumer satisfaction, and follow-up through University athletic departments. Anecdotally - in 10 years, none of the approximately 5,000 students exposed to the program have been accused or charged with sexual/physical assault, harassment or rape, while other non-exposed students at same institutions have been.</p> <p>Pre- and post-test comparisons of some groups have found the program to significantly increase knowledge regarding rape & violence, rape-trauma syndrome and skills for safe dating (unpublished).</p>	<p>Note Authors suggest this program could be readily adapted for use with other high risk groups including military men.</p>
--	--	--	--	--

<p>Hanson KA, Gidycz CA. Evaluation of a Sexual Assault Prevention Program. <i>J of Consulting and Clinical Psychology</i>. 1993; 61(6):1046-1052.</p>	<p>Target Population College women</p>	<p>Program 1 session. Duration not specified.</p> <p>Acquaintance rape prevention program. Included:</p> <ul style="list-style-type: none"> - statistics re prevalence of sexual assault on college campuses - discussion of rape myths/facts - video depicting events leading to acquaintance rape at a college party (including situational variables such as alcohol use, isolation of site where incident occurs, lack of assertiveness) - discussion of rape-preventive measures - a second video modeling rape-protective behaviors (same characters) - further discussion of protective behaviors, as well as strategies for dealing with confrontation/rape threat - information about local sexual assault resources 	<p>Evaluation Subjects: 360 undergraduate women recruited from psychology courses, divided into treatment group (n=181) and non-intervention control group (n = 165). Randomization not mentioned. 94% white.</p> <p>Pre/post; post-test given 9 weeks after intervention.</p> <p><u>Results:</u> No effect on sexual assault incidence among women with a sexual assault history.</p> <p>Reduced incidence of sexual assault among women with no sexual assault history</p> <p>Decrease in dating behaviors associated with acquaintance rape</p> <p>Increase in knowledge about sexual assault</p>	<p>Notes Before the large intervention study, the researchers conducted a small pilot study with college women (n=76) to receive feedback re program helpfulness and clarity, and participants' degree of comfort with the program. Changes to the curriculum were made on the basis of feedback.</p> <p>This is one of very few program evaluations that have sexual assault as an outcome measure.</p>
--	---	---	---	---

Sensitivity and Prevention Program	Target Population	Program	Evaluation		Note
<p>O'Donohue W, Penix TM, Brunswick KA, Development and Evaluation of a Sexual Harassment and Prevention Training Program: A Cognitive Approach. Phase 1 Final Report to NIMH. Unpublished manuscript. <i>(not dated. Latest citation in text: 1998)</i></p>	<p>University employees</p>	<p>Program Video-based workplace sexual harassment intervention.</p> <p>Based on Finkelhor's four preconditions model of etiology of sexual assault, and cognitive-behavioral analyses of aggression & sexual offending.</p> <p>Finkelhor's model (1986): sexual offending is outcome of 4 necessary & sufficient factors: 1) enhanced motivation to harass (e.g., deviant sexual arousal); 2) factors that reduce internal inhibitions (e.g., sexual harassment myth acceptance); 3) factors that reduce external inhibitions (e.g., privacy, after-hours socializing); 4) factors that reduce victim resistance (e.g. poor self-defense strategies).</p> <p>The intervention mainly focuses on factors 1 & 2 above, aiming to modify sexual harassment myths/facts, enhancing victim empathy, decisionmaking/outcome expectancies, and normative expectations regarding harassment and appropriate work relationships.</p> <p>Video format: Combination of expert interview, documentary footage, dramatized vignettes, confessional interviews/personal accounts. Presents realistic scenarios where various positive skills are modeled. Narrated by 1 male & 1 female peer narrator.</p>	<p>Study 1: 120 male & female volunteers from staff & faculty at U of Nevada. Pre-test and immediate post. No control group. Subjects randomly assigned to watch one of 4 segments of video, targeting different outcomes.</p> <p>Results:</p> <ul style="list-style-type: none"> -significant reduction in sexual harassment myth acceptance (same change for m & f) -increase in empathy for victims of harassment (same for m & f) -No significant change in normative perceptions or outcome expectancies. <p>Study 2: 100 m & f volunteers from same context</p> <p>Pre/post test with intervention and placebo group. Post-test 5-7 days after video.</p> <p>Placebo intervention contained information on prevalence, definitions, historical trends re sexual harassment.</p> <p>Results:</p> <ul style="list-style-type: none"> -Significant increase in sexual harassment knowledge - No significant change in attraction to sexual aggression, acceptance of interpersonal violence, myth acceptance, harassment proclivity, adversarial sexual beliefs, hostility toward women, or self-efficacy rating. 		<p>Upon completion of the video, this team conducted focus groups with male and female members of the target workforce. The video was shown in segments, and participants were asked about credibility, informativeness, and perceived likelihood that the video would affect their or others' behavior. After the full focus group, researchers also met independently with members of different minority groups that were represented to obtain confidential feedback re race/ethnic sensitivity/applicability. All focus group participants were also able to provide confidential written comments. Alterations were made to the video as a result of feedback.</p>

Madson L, Shoda J. Identifying Sexual Harassment: A Classroom Activity. <i>Teaching of Psychology</i> . 2002;304- 307.	Target population College students	Program 1 class session. Program goal: to help students clarify what constitutes sexual harassment. Program consisted of discussion of six scenarios which varied in terms of degree to which behavior was intentionally directed at target person; sex of individuals perpetrating and receiving the behavior; relative status of the potential harasser; degree to which the same behavior may have been perceived differently by different people; desirability of the potential harasser; and potential harassment in an educational setting.	Evaluation 63 students in Sexual Behavior and Psychology of Women classes at Mexico State University. Pre-test a few weeks prior to intervention; post-test immediately after. Program increased students' knowledge of what can constitute sexual harassment, and awareness of individual differences in perception.	Materials We have the scenarios.
--	---	---	---	---

Sexual Harassment: Recognition, Action and Prevention Jacobs CD, Bergen MR, Korn D. Impact of a Program to Diminish Gender Insensitivity and Sexual Harassment at a Medical School. <i>Academic Medicine</i> . May 2000; 75(5):464-469.	Target Population Faculty and students; evaluation conducted with faculty	Program Mandatory sexual harassment workshop given to all faculty at Stanford School of Medicine. Workshops focused on improving understanding of what legally constitutes sexual harassment (includes myths/facts, use of scenarios); effects of harassment on individuals and institutions; and development of practical skills and strategies to prevent and interrupt harassment (role play re responding directly to someone who is harassing you; discussion of Stanford resources).	Evaluation All faculty participated in the workshop and were sent surveys in 1994, and were surveyed again in 1995. No control group. Approximately 50% response rate for 1994 survey; and 65% (women) and 57% (men) response rate in 1995. Unclear as to whether 1994 survey was given before intervention. Between 1994 and 1995 surveys: - significantly more faculty agreed that school climate was positive (degree to which faculty feel respected and supported) and cohesive (degree of involvement in and commitment to the group). - significant decrease in degree to which faculty perceived sexual harassment; gender insensitivity and gender discrimination to be problems - marginally significant decrease in reported observations of harassing behavior - no decrease in report of experiencing sexually harassing behaviors	Materials We have this curriculum.	Notes The study also found that subjects who reported experiencing behaviors that met the definition of sexual harassment often did not respond affirmatively to an item which asked if they had experienced "sexual harassment." This points to a need to assess behavior experienced, instead of relying solely on apt labeling on part of subject.
--	---	---	---	---	--

Substance Abuse Prevention Programs – Summary Chart

Program Content	Target population	Evaluation	Materials	Notes
<p>ATLAS (Adolescents Training and Learning to Avoid Steroids)</p> <p>Goldberg L., MacKinnon D.P., Elliot D.L. The Adolescents Training and Learning to Avoid Steroids Program: Preventing Drug Use and Promoting Health Behaviors. <i>Arch Pediatr Adolesc Med.</i> April 2000;154(4):332-338.</p> <p>Goldberg L., Elliot D.L., & Clarke G., et al. The adolescents training and learning to avoid steroids (ATLAS) prevention program: Background and results of a model intervention. <i>Arch Pediatr Adolesc Med.</i> 1996;150: 713-721.</p> <p>Goldberg L., Elliot D.L., Clarke G., MacKinnon D.P., & Moe E., et al. Effects of a Multi-Dimensional Anabolic Steroid Prevention Intervention: The A.T.L.A.S. (Adolescents Training and Learning to Avoid Steroids) Program. <i>Journal of the American Medical Association</i>, 1996;276: 1555-1562.</p> <p>Linn Goldberg, M.D. Division of Health Promotion and Sports Medicine Oregon Health Sciences University (503) 494-8051 goldberl@ohsu.edu www.atlasprogram.com</p>	<p>School-based, 10-session program aimed at reducing athletes' intentions to use, and actual use of, anabolic steroids, alcohol, and other drugs</p> <p>Delivered to school sports team. Implemented by coaches in conjunction with coach-selected peer educators</p> <p>Program capitalizes on team-centered dynamics and uses positive peer pressure, role modeling and role play</p> <p>Program promotes healthy nutrition and exercise behaviors as alternatives to substance use. Key features of the program are after-school curricula/activities, peer leadership and counseling or support.</p>	<p>High school male athletes ages 13-19</p> <p>Rural, suburban and urban</p>	<p>Randomized controlled trial in 31 high schools; 3200 participants.</p> <p><u>1-year follow-up results:</u></p> <p>Reduced steroid use</p> <p>Increased belief that coaches do not condone/tolerate steroid use</p> <p>Reduced use of alcohol and illicit drugs</p> <p>Reduced drinking and driving</p> <p>Increased perceived susceptibility to harmful effects of drugs</p> <p>Improved nutrition and exercise behaviors</p> <p>Increased feeling of athletic self-efficacy</p> <p>Stronger team mentality</p>	<p>\$150 full set</p> <p>This program may be of interest to us for the population it targets, of male athletes –</p>

<p><u>Class Action</u></p> <p>Ann Standing HazelDEN Publishing and Educational Services 1-800-328-9000 astanding@hazelden.org www.hazelden.org</p>	<p>Program</p> <p>Class Action is part of the Project Northland school-based alcohol-use prevention curriculum series that has been found to significantly reduce increased alcohol use and binge drinking in high school students.</p> <p>8-10 session program, based on the social influences theory of behavior change</p> <p>Program uses interactive, peer-led sessions to discuss consequences of substance abuse, thus changing social norms around alcohol use and changing negative peer pressure into positive peer pressure.</p> <p>The Class Action intervention aims to develop resistance, decision-making, social competence and leadership skills. It can be used as part of the Project Northland series or as a stand-alone program.</p>	<p>Target population</p> <p>Grades 9-12; m & f</p>	<p>Evaluation: Randomized controlled trial with 24 school districts; participants followed over 6 years (from 6th to 12th grade).</p> <p>Results: 33% reduction in the usual increase in alcohol use and intentions to use alcohol, through 12th grade</p> <p>50% reduction in binge drinking during high school through 12th grade</p> <p>80% reduction in underage alcohol purchases in off-outlets sale (e.g., liquor and convenience stores)</p>	<p>Materials</p> <p>Teacher training curriculum package (\$69.95)</p>	<p>.</p>
---	---	---	--	--	----------

<p>Project SUCCESS (Schools Using Coordinated Community Efforts to Strengthen Students)</p> <p>Ellen Morehouse, M.S.W., CASAC, CPP Student Assistance Services Corporation (914) 332-1300 sascorp@aol.com www.sascorp.org</p>	<p>Program</p> <p>Project SUCCESS aims to prevent and reduce substance use among high-risk, multiproblem high school students.</p> <p>The program places trained professionals in schools to provide a broad range of substance use prevention and early intervention services. Counselors use a variety of intervention strategies, including: information dissemination; normative and preventive education; counseling and skills training; problem identification and referral; community-based processes; and environmental approaches.</p> <p>Project SUCCESS also links the school to the community's continuum of care when necessary, referring students and families to substance abuse treatment agencies and other human service organizations.</p>	<p>Target population</p> <p>Ages 14-18; male and female;</p> <p>Rural, suburban, and urban alternative high schools</p>	<p>Evaluation:</p> <p>Pre/post with comparison groups</p> <p>Subjects: alternative school youth ages 14-18 (n = 425)</p> <p><u>Results:</u> Program participants showed a 37% overall decrease in substance use, as compared to comparison group subjects. Of those adolescents using substances, 23% of program participants and 5% of comparison group subjects quit using at follow-up.</p> <p>For those adolescents who did not quit using substances, there was a significant reduction in mean substance use ranging between 17% and 26.6% among intervention participants.</p> <p>Posttest data regarding past-month use revealed that of students in the second year of Project SUCCESS (n=78) who reported using at pretest:</p> <ul style="list-style-type: none"> ▪ 33% (15 of 46) reported no longer using alcohol ▪ 45% (18 of 40) reported no longer using marijuana ▪ 23% (11 of 48) reported no longer using tobacco <p>Program was effective with both genders, students from various ethnic groups, and across grade levels from grades 9-12. Project SUCCESS benefited not only students who participated directly in the program but also those students (the comparison group) who participated indirectly by associating with Project SUCCESS students.</p>	<p>Material</p> <p>Manual: \$150</p>	<p>Notes</p> <p>Though this program has various elements that are beyond what we will be doing, we may be able to learn from their implementation manual.</p>
--	--	--	---	---	--

Team Awareness	Program	Target population	Evaluation	Materials
<p>Bennett JB, Lehman WEK, Reynolds GS. Team Awareness for Workplace Substance Abuse Prevention: The Empirical and Conceptual Development of a Training Program. <i>Prevention Science</i>. 2000;1(3):157-172.</p> <p>Joel Bennett, Ph.D. Organizational Wellness & Learning Systems (817) 921-4260 owls@charter.net www.organizationalwellness.com</p> <p>Wayne Lehman, Ph.D. Institute of Behavioral Research Texas Christian University (817) 257-7226 ibr@tcu.edu www.ibr.tcu.edu</p>	<p>Workplace training program that addresses behavioral risks associated with substance abuse among employees, their coworkers and, indirectly, their families.</p> <p>6 modules, conducted in two 4-hour sessions.</p> <p>The program aims to: 1) improve knowledge and attitudes toward alcohol- and drug-related protective factors in the workplace; 2) promote increased communication between workers; and 3) increase peer referral behaviors.</p> <p>Modules cover workplace policy ownership, enabling, stress management, listening skills and peer referral.</p> <p>The program is highly interactive and uses group discussion, communication exercises, a board game, role play and self-assessments.</p>	<p>18-55+; male and female</p> <p>suburban and urban workplaces</p> <p><i>Team Awareness</i> is designed for use in any occupational group where employees interact with or depend on each other to get work done. The training may be particularly effective for safety-sensitive occupations (e.g., emergency response and law enforcement personnel) or where tradition supports coworkers' shared use of alcohol to handle stress or to socialize.</p>	<p>Pre-post design with random assignment of work groups from two samples: a suburban municipal workforce and three high-risk departments from a large municipality. Employees received either <i>Team Awareness</i> (n=254); an enhanced informational training that reviewed policy and EAP services (n=219); or no training (n=235).</p> <p>Subjects were assessed 2 weeks pre and post training, and again at 6 months post training.</p> <p>6-month follow-up results: Compared to the control group, program participants were:</p> <p>Nearly three times less likely to work with or miss work due to a hangover</p> <p>Significantly less likely to come to work under the influence of illicit drugs or alcohol</p> <p>Two times as likely to decrease problem drinking behaviors</p> <p>Significantly more likely to work in groups that encourage coworkers to stop a drinking or drug habit</p> <p>Less likely to drink with coworkers</p>	<p>Free for downloading at www.organizationalwellness.com</p>

Too Good For Drugs (TGFD)	Program	Target population	Evaluation	Materials	Notes
<p>Susan K. Chase Mendez Foundation (800) 750-0986 x 206</p> <p>schase@mendezfoundation.org</p> <p>www.mendezfoundation.org/</p>	<p>School-based, interactive prevention program designed to reduce the intention to use alcohol, tobacco and illicit drugs in middle and high school students.</p> <p>Separate, developmentally appropriate curriculum for each grade level.</p> <p>The program aims to develop: personal and interpersonal skills relating to alcohol, tobacco, and illegal drug use; appropriate attitudes toward alcohol, tobacco, and illegal drug use; knowledge of the negative consequences of alcohol, tobacco, and illegal drug use and benefits of a drug-free lifestyle; positive peer norms</p> <p>The program encourages students to bond with prosocial peers, and engages students through role-play, cooperative learning, games, small group activities and class discussions. TGFD also impacts students through a family component used in each grade level.</p>	<p>5-18 ; Male and Female ; African American Asian American Hispanic/Latino Native Hawaiian and Other Pacific Islander (NHOP) White</p> <p>Rural, suburban and urban schools; optional component for after-school settings</p>	<p>High school studies used a pretest/posttest randomized design. Sample populations included students from one large high school from the nation's 12th largest school district (n = 201) and students from six high schools in a small, rural school district (n = 303).</p> <p><u>Results:</u></p> <p>Reduced intentions to use cigarettes, alcohol, marijuana</p> <p>Reduced intentions to engage in aggressive behavior</p> <p>Improved decisionmaking, goal setting, and peer resistance skills</p> <p>Increased friendships with peers less likely to use alcohol, tobacco, and illegal drugs</p>	<p>\$100-\$130 for individual K-8 kits (see program Web site for details)</p> <p>\$750 for Too Good For Drugs & Violence High School Kit</p> <p>\$595 for Too Good For Drugs & Violence After-School Activities Kit</p> <p>\$250 for Too Good For Drugs & Violence Educators Kit (staff development)</p>	<p>Could find out if we can request only their 12th grade curriculum.</p>

Project Toward No Drug Abuse	Program	Target population	Evaluation	Materials
<p>Sussman S, Dent CW, Craig S. One-Year Outcomes of Project Toward No Drug Abuse. <i>Preventive Medicine</i>. 1998;27(4):632-642.</p> <p>Sussman S, Dent CW, Stacy AW. Project Toward No Drug Abuse: A review of the Findings and Future Directions. <i>Am J Health Behavior</i>. 2002;26(5):354-365.</p> <p>Steve Sussman, Ph.D. Dept. of Preventive Medicine, USC (626) 457-6635 ssussma@hsc.usc.edu</p> <p>www.cccanet.org/Research/Sussman/tnd.htm</p>	<p>Program aims to help high school youth resist substance use.</p> <p>School-based program. Twelve 40- to 50-minute lessons.</p> <p>Include motivational activities, social skills training, and decisionmaking components that are delivered through group discussions, games, role-playing exercise, videos, and student worksheets. Project TND teaches participants increased coping and self-control skills that allow them to:</p> <ul style="list-style-type: none"> - Grasp the cognitive misperceptions that may lead to substance use and express a desire not to abuse substances - Understand the sequence of substance abuse and the consequences of using substances - Correct myths concerning substance use - Demonstrate effective communication, coping, and self-control skills - State a commitment to discuss substance abuse with others 	<p>14-19; Male and Female; Rural, suburban and urban high schools</p>	<p>1997-1998 trial of TND-II (the only version of this program currently disseminated) with 18 alternative high schools (n=1000).</p> <p>A randomized block design. 6 schools were assigned to one of three conditions: (1) standard care (i.e., the control group), (2) a 12-lesson classroom program, or (3) a 12-lesson self-instructional version of the classroom program.</p> <p><u>Results:</u> Project TND-II participants experienced:</p> <p>A reduction in cigarette use of 27%</p> <p>A reduction in marijuana use of 22%</p> <p>A reduction in higher levels of alcohol use of 9%</p> <p>A reduction in "hard drug use of 26%</p> <p>25% reduction in weapons-carrying among males</p>	<p>\$70 Teacher manual</p> <p>\$50 Student workbook (set of 5)</p> <p>\$40 <i>Drugs and Life Dreams</i> video</p>

Healthy Workplace Royer F. Cook, Ph.D. The ISA Group 703-739-0880 rcook@isagroup.com www.centerforworkforcehealth.co m	Program The Healthy Workplace program is a set of 5 distinct workplace substance abuse prevention interventions that reduce unsafe drinking, illegal drug use, and prescription drug abuse while improving the health practices of adult workers. Based on social-cognitive principles of behavior change; presented within health promotion framework Among these 5 interventions, The Working People intervention focuses on alcohol abuse prevention and is appropriate for a young (18-35), blue-collar workforce. (Four 30-minute sessions.) The Power Tools intervention is an eight-session program developed specifically for young blue-collar men. The Healthy Workplace program combines instruction on general health issues with special sessions devoted to alcohol and drug abuse. The program integrates substance abuse prevention material into popular health promotion programs, defusing the stigma that accompanies substance abuse and removing barriers to help-seeking behavior. The program: - Reaches the mainstream of workers through the positive vehicle of health promotion - Raises awareness of the benefits of healthful practices and the hazards of using alcohol, tobacco, and illegal drugs, and misusing legal drugs - Teaches employees specific techniques for improving health and reducing use of alcohol, tobacco, and illegal drugs - Uses videos to raise self-efficacy and provide models for how healthful practices can be embraced and substance abuse reduced	Target population 18-55; male and female; urban and suburban workplaces	Evaluation The Healthy Workplace interventions have been tested with pre-posttest repeated measure designs. In three of the five studies, workers were randomly assigned to the program or a control group. In two studies, the design was quasi-experimental. Sample sizes ranged from 108 ("Working People") to approximately 1,500 ("Prime Life 2000"). <u>Results:</u> The studies of the Healthy Workplace program have typically shown reductions in alcohol and drug use, as well as improvements in other health measures such as stress coping abilities and dietary practices. In the test of the "Working People" intervention, program participants reduced their alcohol consumption by 47% and their number of days of binge drinking (5+ drinks at a time) by 60%. In the test of "Make the Connection," participants showed increases in perceived risks of alcohol or drug abuse and associations between health and alcohol and drug abuse, and decreases in the use of alcohol and drugs for stress relief. In the test of "Prime Life 2000," participants showed reductions in binge drinking and heavy drinking (5+ drinks on 5+ days in the past month).	Materials Materials can be ordered from website. <i>Price info to come.</i>	Note The "Working People" and "Power Tools" intervention materials may be of greatest interest to us, given the populations they target (blue-collar workforce ages 18-35; and young blue collar men, respectively.) Evaluation outcomes for "Power Tools" are not presented.
--	--	---	---	---	--

<p><u>Coping with Work and Family Stress</u></p> <p>David Snow, Ph.D. Dept of Psychiatry, Yale Univ. 203-789-7645 david.snow@yale.edu</p> <p>Susan Zimmerman, LCSW Dept. of Psychiatry Yale Univ. susan.zimmerman@yale.edu</p>	<p>Program A workplace coping skills and substance abuse prevention program</p> <p>16-session weekly group intervention designed to teach employees how to develop and apply effective coping strategies to deal with stressors at work and at home.</p>	<p>Target population</p> <p>18-54; male and female; rural, urban</p>	<p>Evaluation Two studies funded by NIDA and NIAAA assessed the program. Study 1 involved 239 female secretarial and clerical workers in manufacturing, utility, and telecommunication companies. Volunteers were randomly assigned to the intervention or the control group.</p> <p>Study 2 involved 468 male and female employees working at two water companies and one manufacturing plant. The sample included a cross-section of all occupational groups within the sites. Volunteers were randomly assigned within each site to a 16-session coping-skills intervention, an 8-session attention control group, or a no-treatment control condition.</p> <p><u>Results:</u></p> <p>Significant reduction in work and family stressors</p> <p>Significant increase in problem-solving and cognitive coping strategies</p> <p>Significant reduction in the use of avoidance coping strategies</p> <p>Significant increase in social support from supervisors and co-workers</p> <p>Significant reduction in the use of alcohol and other drugs</p> <p>Significant reduction in depression, anxiety, and somatic complaints</p>	<p>Note Given the high stress of military life – may be helpful to see how this program connects coping skills, stress reduction and substance abuse prevention.</p>
--	---	---	---	---